



Australian Government

Department of Health and Ageing

TGA Online Services Manufacturer Information System (MIS)

Lodgement User Guide



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Introduction

Introduction	Welcome to the Therapeutic Goods Administration (TGA), TGA Online Services system. This system has been developed to provide the customers of TGA services with an easy and modern way of conducting business with TGA. There are a number of sub-systems within the TGA Online Services system that provide an electronic interface for many of the business units within TGA.
Overview	This document is a reference guide for the Manufacturer Information System (MIS) a sub-component of the TGA Online Services System. It outlines the MIS sub-system and provides external customers with instructions for using the system.
Who Should Use This Manual	This document is a reference guide for the use of TGA customers, particularly Agents, Manufacturers and Sponsors of Licence Applications, GMP Certifications and GMP Clearances.
How to Use This Manual	This manual has been written for users to view it alongside the Manufacturer Information System web site, to maximise the value of its information. There are three main chapters that cover Licence, GMP Certification and GMP Clearance applications. Each of these chapters is designed to be utilised individually so users can focus on specific types of applications as needed. Other parts of this manual cover details that are generic to the whole MIS such as navigation and help features.
Assumptions	It is assumed that users are familiar with mouse skills and have a basic knowledge of the Web environment. Some Web terminology is explained for users in the “Navigation” Section of this manual.
Help	Help is available for all TGA Online Services systems. For the various forms of help refer to the Help Section in this document.

Overview of the Manufacturer Information System

Introduction	<p>The Manufacturer Information System is a component of the larger TGA Online Services system. The Manufacturer Information System is designed to provide a web-based interface between TGA's clients and the GMP section of TGA. It provides the electronic forms necessary for submitting licences, GMP Certification and GMP Clearance applications. The Manufacturer Information system then provides support to TGA staff in the processing of applications, and once a licence application is successfully processed supports the publishing of the licence to the Australian Manufacturer's Database.</p>
Client access	<p>The Manufacturer Information System also provides the following client access facilities for TGA clients:</p> <ul style="list-style-type: none">• Read only display of Licences, GMP Certifications and GMP Clearance records owned by the client.• The ability to create applications or to clone or vary these entries.
Public access	<p>The system also provides a level of on-line access for members of the public. In the case of the Manufacturer Information System, public access to legally appropriate information via the Internet is limited to the Australian Manufacturers Database which gives basic information on approved Australian Manufacturer Licences.</p>
Benefits	<p>The fundamental business objective of the Manufacturer Information System is to provide an efficient means of managing, tracking and reporting upon the processing and evaluation of applications by clients to have their information recorded on the TGA GMP Register.</p> <p>The Manufacturer Information system will deliver the following business benefits:</p> <ul style="list-style-type: none">• Quicker turn-around of client applications and queries• Greater accessibility to business information• Improved communication between business areas.

Getting Started

Introduction

The TGA Online Services system is available through the Department of Health and Ageing web site. The TGA Online Services web interface conforms with the Department of Health and Ageing web useability standards.

The TGA Online Services Home Page

The TGA Online Services Home Page is available at the following URL:

<http://www.tgasime.health.gov.au/sime/home.nsf>

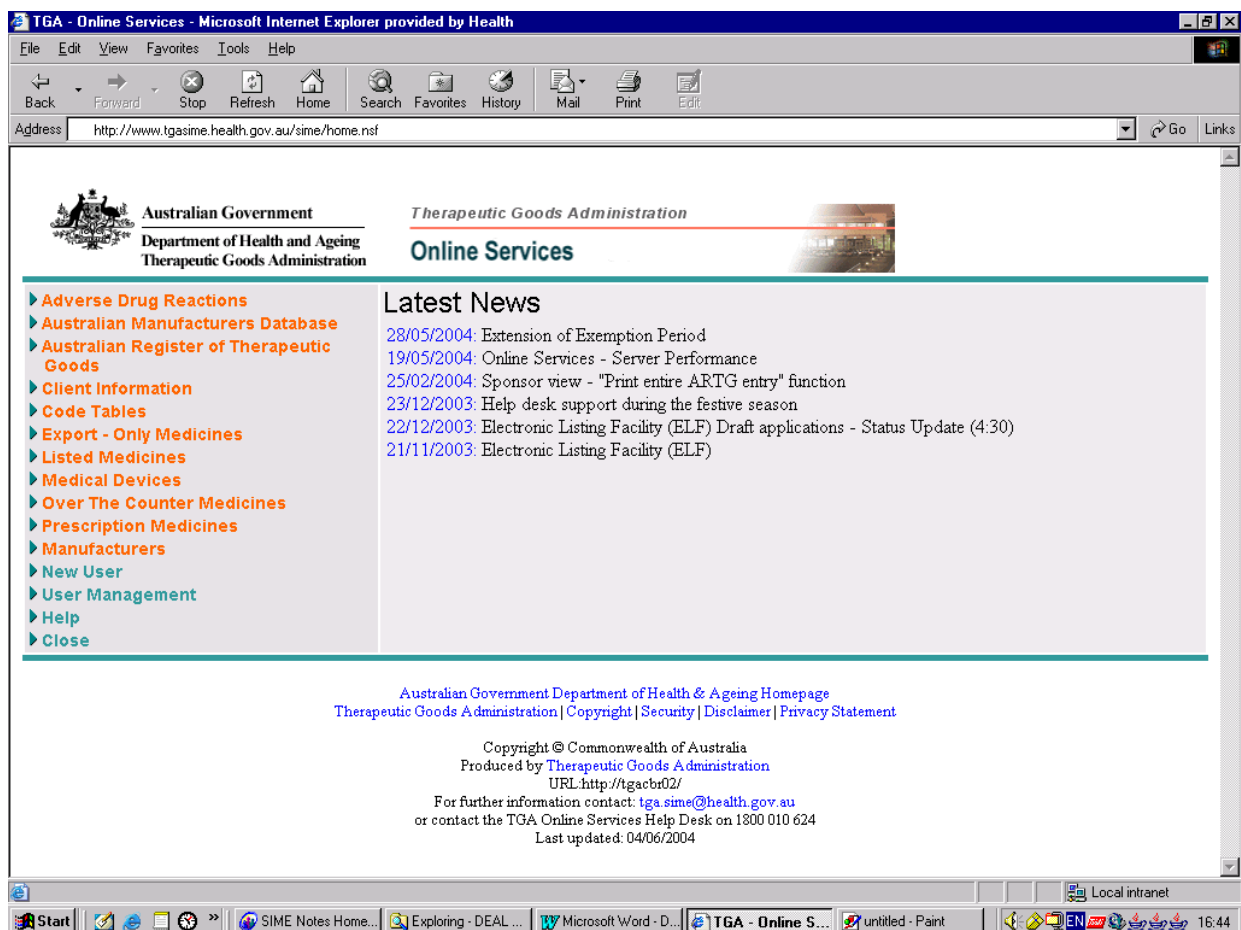


Fig. 1. TGA Online Services Home Page

The TGA Online Services Home Page is publicly accessible. Security will be applied to most of the TGA Online Services system beyond this point based upon the access that users have been granted. Only users who are formally registered with TGA as an “Agent”, “Manufacturer” or a “Sponsor” will be able to access protected MIS data.

**Accessing TGA
Online Services
Systems**

Access to the individual systems is via the TGA Online Services Home Page.

1. Navigate to the TGA Online Services Home Page *(at the URL above)*
 2. Click on the 'Manufacturers' link.
 3. The client will be asked to login entering an appropriate username and password as provided by the TGA. (A new user should click on the "New User" link for information on how to apply to the TGA for access).
 4. The Manufacturers Application Lodgement home page will be displayed.
-

The TGA Online Services Web Environment

Navigation

Introduction

The TGA Online Services system is designed to be easy to use. TGA Online Services looks and works like many other prominent web-based applications, but it is useful to know and understand the function of the controls within the TGA Online Services web pages, particularly those used for navigation.

The information regarding these navigation controls applies in the majority of circumstances. Instances where these navigation features will be nullified or changed in functionality will be advised at the appropriate point in the manual.



The TGA Online Services Home Page Control:

The TGA Online Services Home button is located in the top left of most pages in the system. It consists of the SIME logo. Use of this navigation control will return the user to the TGA Online Services home page. Although the logo is present in the same location on every page in the system, the functionality of the button is only activated on pages where it is sensible to allow users to return directly to the TGA Online Services home page. On other pages, such as those that are part of application forms, this functionality is disabled to protect the integrity of information entered into the TGA Online Services interface.

A small, rounded rectangular button with a light blue background and a thin grey border. The word 'Help' is written in a bold, blue, sans-serif font in the center.

The System Help Button:

This button is located in the top right of all TGA Online Services pages. Clicking on this button will open a new window with the appropriate help file for the page that the user is currently viewing.

A small, rounded rectangular button with a light blue background and a thin grey border. The word 'Search' is written in a bold, blue, sans-serif font in the center.

The Search Button:

The search button is available when viewing lists of applications. It provides the user with the ability to conduct searches based upon application number, agent's information, manufacturer's information etc.

A small, rounded rectangular button with a light blue background and a thin grey border. The word 'Previous' is written in a bold, blue, sans-serif font in the center.

A small, rounded rectangular button with a light blue background and a thin grey border. The word 'Next' is written in a bold, blue, sans-serif font in the center.

The Previous and Next Buttons:

These buttons will appear on pages that contain lists of applications that exceed a reasonable page length. They allow the user to navigate forwards or backwards through the list.

Home**The Home Button:**

The home button is different from the TGA Online Services Home button. It will appear in application forms and at the top and bottom of list pages. Clicking on this button will return the user to the Manufacturers Application Lodgement home page.

Refresh**The Refresh Button:**

The refresh button is available when viewing lists of submitted or approved applications. It provides the user with the ability to refresh the details being displayed on the current screen.

Close**The Close Button:**

The close button is available when viewing or editing an application. When viewing, it returns control to the previous list screen. In edit mode, it saves any changes made to the application and returns to the Manufacturers Application Lodgement home page.

View Entire App**The View Entire Application Button:**

This button is available when viewing an application in detail through the individual pages of an application form. Clicking this button will display the entire application in a dialog box in a “printer friendly” format which can be printed by clicking on the “Print” button.

New Draft Copy**The New Draft Copy Button:**

This button is available when viewing an application in detail through the individual pages of an application form. Clicking this button will create a new application with the fields initialised to the values contained in the current selected application.

Withdraw**The Withdraw Button:**

This button is available when viewing an application with a submit status. Clicking this button will result in the application being withdrawn from the system. The status of the application will be changed to “Pending Withdrawal”. Once the withdrawal is completed by TGA, the status will be changed to “Withdrawn”.

Edit**The Edit Button:**

This button is available when viewing a draft application. Clicking on the button changes the appropriate form fields from read mode to being editable so that changes can be made.

Save**The Save Button:**

This button is available when editing an application. Clicking on the save button saves the changes as a draft application. The application remains on the screen in edit mode and more changes can be made.

Validate**The Validate Button:**

This button is available when editing an application. The button allows a user to validate the information that they have supplied in the application prior to submission. If a particular mandatory field in the application has not been completed, or if a particular combination of information supplied creates a breach of TGA business rules, the application will fail validation. If an application does fail validation, detailed messages informing the user of the problem are displayed in a pop-up dialog box. Clicking on an error message displays the appropriate place in the application so that it can be corrected. An application can not be submitted until it has passed validation.

Delete**The Delete Button:**

This button is available when editing an application. Clicking on the button displays a dialog box asking for confirmation of the delete. Clicking on “OK” will permanently remove the application from the system. Clicking on “Cancel” will return to the draft application with no action taking place.

Submit**The Submit Button:**

This button is available when editing an application. The button provides the user with a means to be able to submit the application to the TGA. The system will automatically do a validation when an application is submitted, thereby preventing invalid applications from being submitted.

Vary Application**The Vary Application Button:**

This button is available when viewing approved applications. Clicking on the button creates a new draft application initialised to the values of the current application. Once finalised, the new application will replace the old one.

Create Request**The Create Request Button:**

This button is available when viewing approved applications. Clicking on the button creates a request for action by TGA. The request can be a request for copies of a document, an update of evidence or simply a general enquiry.

Print Preview**The Print Preview Button:**

This button is available when creating a declaration. Clicking this button will display the declaration in a dialog box in a “printer friendly” format which can be printed by clicking on the “Print” button.

Mandatory Information

In all of the application forms of the MIS system, there are certain information fields that are mandatory. The mandatory fields are prefixed with a red coloured star (★), and are always required otherwise the application will not pass validation.

Help

Introduction

Throughout each of the TGA Online Services systems, on-line help is available either through the help button in the top right corner of the page, or through help buttons located next to particular input fields on the application forms.

Accessing Help

Accessing help through either the main page button or a button on an application form will open a new window to display a context sensitive help topic. If the main help button is used, the help file will describe the general use of the page that the user is currently viewing. If the help button beside an input field is used, the help file will display detailed information about that field.

Help Conventions:

Throughout the on-line help system, certain actions and objects are indicated in the following ways:

- On screen button names are placed in single quotes. For example, click on 'OK', means click once on the button labelled OK.
 - Keyboard key names are placed in greater/less than symbols. For example, press <CTRL>, means press the control (CTRL) key on your keyboard.
 - Important messages and notes are written in italics. For example:
Note: These notes should always be read!
 - Italics are also used for field descriptions. For example, *Field 1*, refers to the first field within the on-line form.
-

Help Desk

If at any time you are experiencing problems using the MIS system or need further assistance, contact the MIS Help Desk:

- E-mail: tgasime@health.gov.au
Please include the word **MIS** in the subject line of the E-mail.
- Phone: 1800 010 624

The Help Desk operates Monday to Friday between the hours of 8:30am – 5:00pm EST.

If you are experiencing problems with your User Account or accessing the TGA Online Services system, please contact the TGA Online Services Help Desk:

- E-mail: tgasime@health.gov.au
Please include the words **TGA Online Services** in the subject line of the E-mail.
 - Phone: 1800 010 624
-

Manufacturers Application Lodgement

The TGA Online Services MIS Home Page

The TGA Online Services MIS Manufacturers Application Lodgement home page is accessed by clicking on “Manufacturers” on the TGA Online Services Home Page.



Fig. 2. The TGA Online Services MIS Manufacturers Application Lodgement Home Page

Special Home Page Buttons

The TGA Online Services MIS home page has a number of special navigation buttons.

User Documentation

The User Documentation Button:

This button will open a new window which displays user documentation information.

What's New

The What's New Button:

This button will open a new window which displays recent news regarding the system. The information on the page is updated regularly and should be revisited often.

Lodge Supporting Documents

The Lodge Supporting Documents Button:

This button will open a new window which allows the user to lodge with the TGA, documents in support of an existing application.

Licensing of Australian Manufacturers

Licence Application Processing

Draft Applications

To create a new licence application :-

- 1) Click on *Create New Licence Application* on the Manufacturers Application Lodgement home page (Pg 10).
- 2) A new application entry form will be opened (Pg 15). Enter the *Applicant's Own Reference* information if required.
- 3) Enter the *Client Details* (Pg 17), *Primary Site* (Pg 19), *Secondary Site* (Pg 22) and *Supporting Documents* (Pg 24) as described below.
- 4) Save the application as a draft copy by clicking on the "Save" button.

To edit an existing draft licence application :-

- 1) Click on *View Draft Licence Applications* on the Manufacturers Application Lodgement home page (Pg 10).
- 2) A list of all the draft applications currently in the system will be displayed (Pg 29). To view the application, click on its *Tracking Number*. If the number of applications exceeds the page size, use the "Previous" and "Next" buttons to page backwards and forwards. Alternatively, search for the required application using the "Search" button.
- 3) Once the application has been displayed, it can be changed by clicking on the "Edit" button (Pg 15). The application will be opened in edit mode and the changes can be made.
- 4) Save the changes by clicking on the "Save" button.

To input the application details :-

- 1) The application form is divided into a number of individual pages. When first displaying the form, the *Client Details* (Pg 17) page is shown.
- 2) Clicking on the other page buttons will open them for editing. The other individual pages include *Primary Site* (Pg 19), *Secondary Site* (Pg 22) and *Supporting Documents* (Pg 24).
- 3) All fields marked with a red star are mandatory and must be entered.

To view and print an application :-

- 1) To view the entire application, click on "View Entire App". A new window will open which shows the full application in a "printer friendly" view.
- 2) Clicking on "Print" will print out the full application.

Draft Applications**(continued)**To save, save and close or to exit without saving :-

- 1) To save an application without exiting, click on “Save”. Clicking on “Close” will also save the application, but will then exit to the Manufacturers Application Lodgement home page (Pg 10).
- 2) To exit without saving any changes made to the currently displayed page, click on “Home”. Control will be returned to the Manufacturers Application Lodgement home page (Pg 10).

To validate an application :-

- 1) Once all the data has been entered into the form, the application should be validated by clicking on “Validate”.
- 2) Any errors will be listed on the screen via a dialog box. Clicking on an error displays the corresponding place in the application so that it can be corrected.
- 3) All applications must pass validation successfully before they can be submitted.

ApplicationsTo submit an application :-

- 1) To submit an application, you must be in “edit” mode. Click on the “Submit” button.
- 2) All applications are automatically validated and, if errors are found, a dialog box will be displayed listing the errors. Clicking on an error will position the application in the appropriate place so that it can be corrected.
- 3) When submitting an application, a dialog box appears (Pg 32) requesting a further three steps be actioned as follows:
 - *Step 1 - Fees and Payments* (Pg 33).
 - *Step 2 - Declaration* (Pg 34).
 - *Step 3 - Tax Invoice* (Pg on page 35).
 Click on the “Continue” button to continue.
- 4) *Fees and Payments* (Pg 33). The cost of the application is displayed and an option to select a method of payment. If the cheque option is taken, then the cheque number and the bank must be entered.
- 5) *Declaration* (Pg 34). A declaration form is displayed with details taken from the application. If required, the details can be changed before continuing. After clicking on “Next”, a “printer friendly” version is displayed which can be printed by clicking on “Print”. The printed declaration must be signed, witnessed and dated and one copy must be faxed to TGA.
- 6) *Tax Invoice* (Pg 35). A tax invoice is displayed with details taken from the application. It must be checked to ensure it is correct. After clicking on “Next”, a “printer friendly” version is displayed which can be printed by clicking on “Print”. A copy of the printed tax invoice must be faxed to TGA. Credit card details will have to be filled in if paying by credit card.
- 7) Click on “Finish” to complete the submission.

**Applications
(continued)**To view the progress of an application :-

- 1) Click on *View Submitted Licence Applications* on the Manufacturers Application Lodgement home page (Pg 10).
- 2) A list of all the submitted applications currently in the system will be displayed (Pg 36). The first column is the applications status (Pg 100) which indicates the progress of the application. To view the application, click on its *Status* (Pg 37). If the number of applications exceeds the page size, use the “Previous” and “Next” buttons to page backwards and forwards. Alternatively, search for the required application using the “Search” button. An application in submission status cannot be changed. It can however, be withdrawn and a new application made.
- 3) Clicking on “New Draft Copy” will result in a new draft application being created with the details initialised to the values in the current application.

To withdraw an application :-

- 1) Click on *View Submitted Licence Applications* on the Manufacturers Application Lodgement home page (Pg 10).
- 2) A list of all the submitted applications currently in the system will be displayed (Pg 36). The first column is the applications status (Pg 100) which indicates the progress of the application. To view the application, click on its *Status* (Pg 37). Click on “Withdraw” to withdraw the application.
- 3) A dialog box will pop up asking for confirmation of the withdrawal. Click on “OK” to continue.
- 4) The status of the application will be changed to Pending Withdrawal (Pg 100).

**Approved
Licences**To view an approved licence :-

- 1) Click on *View Approved Licences* on the Manufacturers Application Lodgement home page (Pg 10). Alternatively, click on *View All TGA Data* (Pg 97) and then select “Licences”.
- 2) A list of all the approved licences currently in the system and owned by the user, will be displayed (Pg 40). To view the licence, click on its *Licence Number* (Tracking Number) (Pg 41). If the number of licences exceeds the page size, use the “Previous” and “Next” buttons to page backwards and forwards. Alternatively, search for the required licence using the “Search” button.

**Approved
Licences
(continued)**To vary a licence :-

- 1) Approved licences cannot be changed. They can however, have their status changed by clicking on “Vary Application”. This option is used Suspend, Cancel or Re-activate a licence. A new draft application is created which, when finalised by the TGA, will result in the requested status change (Pg 100).
 - 2) Click on *View Approved Licences* on the Manufacturers Application Lodgement home page (Pg 10). Alternatively, click on *View All TGA Data* (Pg 97) and then select “Licences”.
 - 3) A list of all the approved licences currently in the system and owned by the user, will be displayed (Pg 40). To view the licence, click on its *Licence Number* (Tracking Number) (Pg 41).
 - 4) A new application will be created by clicking on “Vary Application”. The new application, once finalised by the TGA, will cause the details to be updated on the Licence. If you want to create a brand new application based on the same details of the current record, then use the “New Draft Copy” option.
-

New Licence Application

Fig. 3. New Licence Application

Application Details

This form is used to complete a new licence application or a variation to an existing approved licence.

Read Only Fields

Status is always “Draft” (Pg 100).

Tracking Number is created by the system once the application has been saved or submitted. It is a unique number which is attached to the application and is used for all future tracking of the application through the system.

The following fields are only displayed when creating a **variation**.

Current Tracking Number is the tracking number of the original application.

New Tracking Number is the new tracking number created for this variation.

Editable Fields The following fields are editable when creating an application or editing an existing draft application. These fields become non-editable once the application has been submitted.

Applicant's Own Ref is an editable field in which the applicant can place any reference information that will help them to identify the application.

The following fields are only displayed when creating a **variation**.

Change Details/Status Indicator indicates to the system whether the variation is to change the details of the application to change its status (Pg 100).

Other *Client Details, Primary Site, Secondary Site, Supporting Documents and Status* (Pg 100) are covered in the next sections.

Fig. 4. Licence Application – Client Details

Client Details This form is used to input the client details.

Read Only Fields *Applicant's Name* is the name associated with the user currently signed in.

Client Id is the id of the applicant, as recorded by the TGA in the Client System.

Suburb, State, Post Code, Phone & Fax are the remaining address details associated with the first line of address that was selected.

Editable Fields *Address* is the first line of the applicant's address associated with the user currently signed in. If there is more than one address associated, a drop down list is displayed so that the correct one can be selected.

Email is the applicant's email address and is used by the TGA for any subsequent correspondence.

Manufacturer Indicator is a radio button selection to indicate whether the manufacturer is known by TGA and therefore is registered or is new.

**Editable Fields
(continued)****Existing manufacturer :-**

Search is a facility to search on all or part of the manufacturer's name. A separate dialog box pops up in which the search criteria can be entered. A list of matches are then displayed from where the required manufacturer can be selected.

Client Id & Client ABN are the client details of the manufacturer selected.

New Manufacturer :-

Client Name is the name of the manufacturer.

ACN or ABN is the manufacturer's ACN or ABN number.

Address, Suburb, State, Post Code & Country are the address details of the manufacturer.

Billing details :-

Address, Suburb, State, Post Code & Country are the billing address details of the application if different from the main address. The fields are optional but, if one is entered, they must all be entered.

Licence Application - Microsoft Internet Explorer provided by Health

File Edit View Favorites Tools Help

Back Forward Stop Refresh Home Search Favorites History Mail Print Edit

Address <http://tgacbr02/sime/mis/lodge.nst/0/6F69F59C2D918FCBCA256EAF001FA95A?EditDocument> Go Links

Client Details Primary Site Secondary Site Supporting Documents

★ Is this application for the collection of fresh blood components? ☐ Yes ☒ No

☒ Secondary Site ☐ Primary Site

★ Primary Licence No:

Primary Site Details

☐ Existing Site ☒ New Site

New Site

★ Street Address:

★ Suburb: ★ State:

★ Post Code: Country:

★ Contact Name:

★ Phone: ★ Fax:

Mobile:

★ Email:

★ Person in charge of Quality Control:

★ CV Attachment:

Add Attachment Remove Attachment

★ Person in charge of Production:

★ CV Attachment:

Add Attachment Remove Attachment

★ Authorised Person for Release:

Manufacturing Items

Manufacturer Types	Sterility	Manufacturing Class	Dosage Form	Product Category	Manufacturing Steps

Add Remove

Application loaded successfully.

Start SIME Help [Ge...] Licence Ap... Exploring - Ima... Microsoft Word... 008_SIME_MI... Document - Lic... Local intranet 16:31

Fig. 5. Licence Application – Primary Site

Primary Site This form is used to input the primary site details.

Read Only Fields **Existing Site :-**

Suburb, State, Post Code & Country are the remaining address details associated with the first line of address that was selected.

Editable Fields *Blood Component* is a radio button selection which indicates whether the application is for the collection of blood components or not.

Site is a radio button selection to indicate whether this is a primary or secondary site. These buttons are only displayed if *Blood Component* was set to “Yes”.

Primary Licence No is the licence number of the primary site. Only displayed if *Blood Component* was set to “Yes” and *Site* is set to “Secondary Site”.

Primary Site Details :-

Site Indicator is a radio button selection to indicate whether the site currently exists in the system or is new.

Existing Site :-

Street Address is the first line of the primary address. If there is more than one address available, a drop down list is displayed so that the correct one can be selected.

New Site :-

Street Address, Suburb, State, Post Code & Country are the address details of the primary site. This must be a street address.

Contact Details :-

Contact Name is the name of the contact person.

Phone, Fax & Mobile are the contact details of the contact person.

Email is the contact person's email address.

Quality Control is the name of the person in charge of quality control.

CV Attachment is the CV of the person in charge of quality control. An *Add Attachment* button is displayed which brings up a dialog box whereby the CV can be browsed and attached. A *Remove Attachment* button is also displayed which removes the attachment. Clicking on the CV will open it in a new window.

Production is the name of the person in charge of production.

CV Attachment is the CV of the person in charge of production. An *Add Attachment* button is displayed which brings up a dialog box whereby the CV can be browsed and attached. A *Remove Attachment* button is also displayed which removes the attachment. Clicking on the CV will open it in a new window.

Editable Fields (continued) *Authorised For Release* is the name of the person who is authorised to release.

Manufacturing Items (Pg 99) :-

Add is a button which, when clicked on, brings up a dialog box to enter the item details. Fields displayed are *Manufacturing Type*, *Sterility*, *Manufacturing Class*, *Dosage Form*, *Product Category* & *Manufacturing Step*. All fields can be populated from the drop down list or, if it is a new item, by typing in the details. The *Manufacturing Type* selected refines what values are permitted for the remaining entries. At least one *Manufacturing Item* must be entered.

Remove is a button which, when clicked, will remove unwanted items. Each item listed has a checkbox in front of it which must be clicked first. All items with a clicked checkbox are removed.

Web Page Dialog

Secondary Site

Applicant's Own Ref: 1234
Tracking Number: MI-10062004-LI-000659-2

Secondary Site Details

☐ Existing Site ☒ New Site

New Site

★ Street Address:

★ Suburb: ★ State:

★ Post Code: Country:

★ Contact Name:

★ Phone: ★ Fax:

Mobile:

★ Email:

Person in charge of Quality Control:

Person in charge of Production:

Authorised Person for Release:

Manufacturing Items

Manufacturer Types	Sterility	Manufacturing Class	Dosage Form	Product Category	Manufacturing Steps

Add Remove

Save Site Close

Fig. 6. Licence Application – Secondary Site

Secondary Site This form is used to input the secondary site details.

Read Only Fields **Existing Site :-**

Suburb, State, Post Code & Country are the remaining address details associated with the first line of address that was selected.

Editable Fields Secondary Site Details :-

Site Indicator is a radio button selection to indicate whether the site currently exists in the system or is new.

Existing Site :-

Street Address is the first line of the secondary address. If there is more than one address available, a drop down list is displayed so that the correct one can be selected.

New Site :-

Street Address, Suburb, State, Post Code & Country are the address details of the secondary site.

Contact Details :-

Contact Name is the name of the contact person.

Phone, Fax & Mobile are the contact details of the contact person.

Email is the contact person's email address.

Quality Control is the name of the person in charge of quality control.

Production is the name of the person in charge of production.

Authorised For Release is the name of the person who is authorised to release.

Manufacturing Items (Pg 99) :-

Add is a button which, when clicked on, brings up a dialog box to enter the item details. Fields displayed are *Manufacturing Type, Sterility, Manufacturing Class, Dosage Form, Product Category & Manufacturing Step*. All fields can be populated from the drop down list or, if it is a new item, by typing in the details. The *Manufacturing Type* selected refines what values are permitted for the remaining entries. At least one *Manufacturing Item* must be entered.

Remove is a button which, when clicked, will remove unwanted items. Each item listed has a checkbox in front of it which must be clicked first. All items with a clicked checkbox are removed.

Licence Application - Microsoft Internet Explorer provided by Health

File Edit View Favorites Tools Help

Back Forward Stop Refresh Home Search Favorites History Mail Print Edit

Address <http://tgacbr02/sime/mis/lodge.nsf/0/6F69F59C2D918FCBCA256EAF001FA95A?EditDocument> Go Links

Applicant's Own Ref:

Status:

Tracking Number:

Client Details Primary Site Secondary Site Supporting Documents

An electronic copy of your Site Master File, Quality Manual or Technical Master File MUST support this application or it will not be valid. However you may also provide a hardcopy of the files if an electronic one is not available. For electronic attachment please limit file size to less than 1mb.

Electronic Document List

Paper Document List

Document Type	Description	Method	Date

Application loaded successfully.

Start SIME Help (...) Licence ... Exploring - I... Microsoft W... 010_SIME... Document - ... Local intranet 17:14

Fig. 7. Licence Application – Supporting Documents

Supporting Documents

This form is used to input the supporting documents.

Editable Fields**Electronic Document List :-**

Add Attachment is a button which, when clicked on, brings up a dialog box whereby the document can be browsed and attached. At least one electronic or paper document (see below) must be entered. Clicking on a document will open the document in a new window.

Remove Attachment is a button which, when clicked on, can be used to remove unwanted attachments. Each attachment listed has a checkbox in front of it which must be clicked first. All attachments with a clicked checkbox are removed.

Editable Fields
(continued)**Paper Document List :-**

Add is a button which, when clicked on, brings up a dialog box whereby the document details can be entered. Fields displayed are *Document Type*, *Description*, *Method of Submission* & *Date Sent*. All fields are mandatory. *Document Type* can be selected from a drop down list or typed in. *Method of Submission* is selected by choosing one of the available radio buttons (Fax/Post/Courier). A convenient click on calendar has been included in the dialog box for *Date Sent*. At least one electronic (see above) or paper document must be entered.

Remove is a button which, when clicked on, can be used to remove unwanted entries. Each entry listed has a checkbox in front of it which must be clicked first. All entries with a clicked checkbox are removed.

Microsoft Internet Explorer provided by Health

File Edit View Favorites Tools Help

Back Forward Stop Refresh Home Search Favorites History Mail Print Edit

Address <http://tgacbr02/sime/mis/lodge.nsf/0/B2FC53644BF250EFC256E8D0004E6877E> Go Links

TGA THERAPEUTIC GOODS ADMINISTRATION

SIME Variation: Licence Application [Help](#)

[Save](#) [Close](#) [Validate](#) [Delete](#) [Submit](#) [Home](#)

Applicant's Ref:

Status: Draft

Current Tracking Number: MI-20042004-LI-000278-2

New Tracking Number: MI-24062004-LI-000667-2

☐ Change Details ☒ Change Status

Client Details Status

Select new status: ☒ Suspend ☐ Cancel ☐ Re-activate

Description:

Variation loaded successfully.

Start Workspace - Lotus ... Variation: Licenc... Exploring - User Do... Microsoft Word - SI... Document - Licence... Local intranet 11:46

Fig. 8. Licence Application – Status

Status This form is used to indicate the change in status required to the current licence.

Editable Fields *Select New Status* (Pg 100) is a radio button option to select the status that is required.

Description is a general comment as to why the change to the status is required and any additional information that may be relevant.

Variation Licence Application

Fig. 9. Variation Licence Application

Application Details

This form is used to create a variation application for an existing licence.

Read Only Fields

Status is always “Draft” (Pg 100).

Current Tracking Number is the tracking number of the original application.

New Tracking Number is the new tracking number created for this variation.

Editable fields

The following fields are editable when creating a variation. They become non-editable once the application has been submitted.

Applicant's Own Ref is an editable field in which the applicant can place any reference information that will help them to identify the application.

Change Details/Status Indicator (Pg 100) indicates to the system whether the variation is to change the details of the application to change its status.

Other

*Client Details, Primary Site, Secondary Site, Supporting Documents and Status (Pg 100) are as per **New Licence Application**.*

View Draft Licence Applications

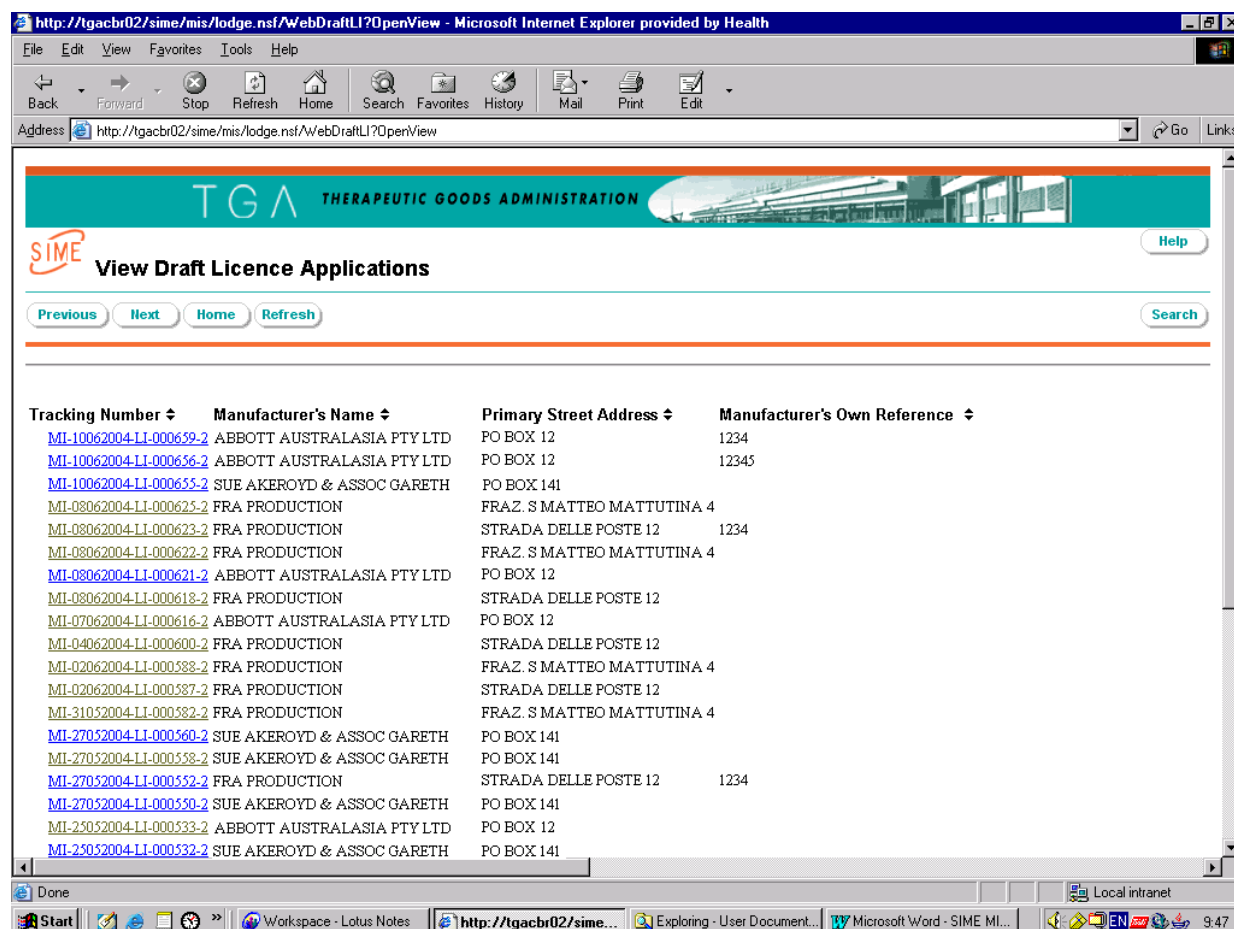


Fig. 10. View Draft Licence Applications List

Draft Licence List

This screen lists all the draft licence applications currently in the system. Clicking on a tracking number will open that application.

Read Only Fields

Tracking Number is created by the system once the application has been saved or submitted. It is a unique number which is attached to the application and is used for all future tracking of the application through the system. Clicking on the Tracking Number opens the draft application for viewing.

Manufacturer's Name is the name of the manufacturer associated with the application.

Primary Street Address is the first line of the primary site's address.

Manufacturer's Own Reference is the applicant's own reference information that may help in identifying the application.

TGA THERAPEUTIC GOODS ADMINISTRATION

SIME Licence Application

[Edit](#)
[Close](#)
[View Entire App](#)
[New Draft Copy](#)
[Home](#)

Applicant's Own Ref: 123456789
 Status: Draft
 Tracking Number: MI-02062004-LI-000587-2

Client Details | Primary Site | Secondary Site | Supporting Documents

Applicant

Applicant Name: Valued Client
 Client Id: 9999999
 Address: PO Box 1234
 Suburb: Melbourne State: VIC
 Postcode: 3000 Country: Australia
 Phone: Fax:
 Email: Staff@email.com

☒ Existing Manufacturer
 ☐ New Manufacturer

Application loaded successfully.

Fig. 11. View Draft Licence Application

Draft Licence Application

This form is used to view an existing draft licence application that was previously saved in draft status.

Read Only Fields

Status is always “Draft” (Pg 100).

Tracking Number is created by the system once the application has been saved or submitted. It is a unique number which is attached to the application and is used for all future tracking of the application through the system.

Editable fields

The following fields are editable when creating an application or editing an existing draft application. They become non-editable once the application has been submitted.

Applicant's Own Ref is an editable field in which the applicant can place any reference information that will help them to identify the application.

The following fields are only displayed when creating a **variation**.

Change Details/Status Indicator (Pg 100) indicates to the system whether the variation is to change the details of the application to change its status.

Other

Client Details, Primary Site, Secondary Site, Supporting Documents and Status (Pg 100) are as per **New Licence Application**.

To Submit A Licence Application

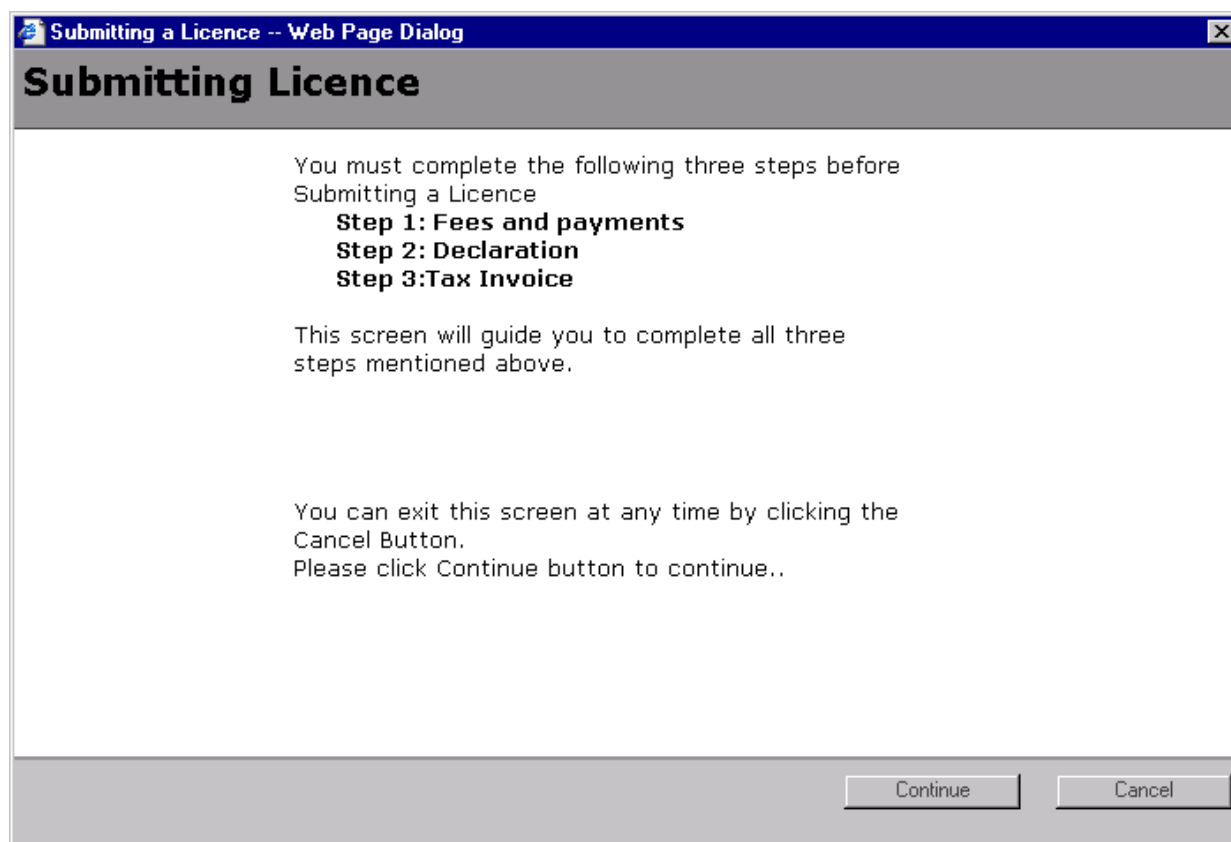


Fig. 12. Submitted Licence

Submitted Licence Steps

When submitting an application, a popup box appears requesting a further three steps be actioned as follows:

Step 1 - Fees and Payments

Step 2 - Declaration

Step 3 - Tax Invoice

Fig. 13. Fees and Payments

Fees and Payments

All licence applications are subject to a fee. This screen allows the user to nominate how payment will be made.

NOTE: If *Visa*, *Bank Card* or *Mastercard* is selected, the payment details must be entered on the *Tax Invoice* (see below). Card details are NOT kept on the system.

Read Only Fields

Fees contains the fee applicable for the type of application.
Payable/Mail To are the details of who the cheque must be made payable to and where to send it.

Editable Fields

Payment Type indicates the payment type. Values are Cheque, Visa, Bank Card & Mastercard.
Cheque No: (Only displayed if Payment Type is CHEQUE) Number of the cheque being sent as payment.
Bank: (Only displayed if Payment Type is CHEQUE) Editable field. Name of the bank the cheque has been drawn on.

Submitting a Licence -- Web Page Dialog

Submitting Licence Declaration

Certification in Relation to Persons Involved with the Applicant for a Licence to Manufacture Therapeutic Goods and Other Persons - Australian Manufacture.

I, A Valued Client hold the position of Chairman in MY Company Pty Ltd at Address for Company understand that the certification below is made for the purpose of assisting the Secretary of the Commonwealth Department of Health and Ageing or her delegate to consider whether the applicant

I/ A Valued Client or a licence to manufacture therapeutic goods the Applicant), persons who participate in, or are likely to participate in, managing the Applicant's affairs (Applicant Managers) and persons who have, or are likely to have, effective control over the Applicant (Applicant Controllers) are fit and proper persons for the purposes of section 38 of the Therapeutic Goods Act 1989, an extract of which is attached.

I hereby certify that:

(a) there has been no suspension or revocation of a manufacturing licence or conformity assessment certificate (however described) issued to the Applicant, any Applicant Manager or Applicant Controller, any other person who controls the Applicant or any Applicant Manager or Applicant Controller (either directly or indirectly through one or more interposed entities) or any person whom the Applicant or any Applicant Manager or Applicant Controller controlled (either directly or indirectly through one or more interposed entities) at the time of the suspension or revocation;

<< Previous Next >> Cancel

Fig. 14. Declaration

- Declaration** This form is used to create a declaration for a licence to manufacture therapeutic goods. The form must, after completion, be printed, signed and one copy sent to TGA.
- Editable Fields**
- Applicant's Name.* Name of person making the application. To be entered in two places.
 - Position.* The position of the applicant in the company.
 - Company Name.* Name of the company.
 - Applicant's Address.* Company's address.
 - Optional Further Information.* Any additional information that relates to the application.

Submitting Licence Tax Invoice

Tax Invoice

This document will be a tax invoice for GST when you make payment.
Please read the information below regarding your payment and ensure it is true and correct.

Application Details

Tracking Number: MI-27052004-LI-000550-2

Application For:

Applicant's Own Reference:

Applicant's Details

Manufacturer Name: MY Company Pty Ltd

Manufacturer ID: 213

Contact Details:

Contact Name: A Valued Client

Contact Email: Staff@email.com

Phone:

Fax:

<< Previous Next >> Cancel

Fig. 15. Tax Invoice

Tax Invoice This form is used to create a tax invoice for a licence to manufacture therapeutic goods. The form must, after completion, be printed and one copy sent to TGA.

Read Only Fields *All Fields Except Card Details:* Populated from the contents of the application. This form is the *Tax Invoice for GST* once payment has been made. The details must be read to ensure it is correct. If not, the submission can be cancelled and the application changed to reflect the correct information. Submission can then be done again.

Card Details: (Only displayed if VISA, BANK CARD or MASTERCARD is selected as the Payment Type) Card information written on the printed version of the Tax Invoice will ONLY be used to make payment and is NOT retained in the system.

Card Holders Signature: After clicking *Next* on the *Tax Invoice* page, a "printer friendly" version is displayed which must be printed. The printed page must be signed and faxed to TGA.

View Submitted Licence Applications

TGA THERAPEUTIC GOODS ADMINISTRATION

SIME View Submitted Licence Applications

Previous Next Home Refresh Search

Status	Tracking Number	Manufacturer's Name	Primary Street Address	Received
Active	MI-20042004-LI-000278-2	A C I BLOWPAK VICTORIA (Australia)	44	20/04/2004
Active	MI-20042004-LI-000278-2	A C I BLOWPAK VICTORIA (Australia)	44	20/04/2004
Active	MI-20042004-LI-000278-2	A C I BLOWPAK VICTORIA (Australia)	44	20/04/2004
Submitted	MI-05052004-LI-000444-2	ANTHOEYR INSTRUMENTATION DENTAIRE (France)	q1 q1	05/05/2004
Under Review	MI-05052004-LI-900007-2	BULLIVANTS NATURAL HEALTH PRODUCTS PTY. LIMITED (Australia)	87 YARRAMAN PLACE	05/05/2004
Under Review	MI-05052004-LI-900006-2	BULLIVANTS NATURAL HEALTH PRODUCTS PTY. LIMITED (Australia)	87 YARRAMAN PLACE	05/05/2004
Submitted	MI-05052004-MTLI-000002-2	A C I BLOWPAK VICTORIA (Australia)	44	20/04/2004
Active	MI-20042004-LI-000278-2	A C I BLOWPAK VICTORIA (Australia)	44	20/04/2004
Active	MI-20042004-LI-000278-2	A C I BLOWPAK VICTORIA (Australia)	44	20/04/2004
Active	MI-20042004-LI-000278-2	A C I BLOWPAK VICTORIA (Australia)	44	20/04/2004
Active	MI-20042004-LI-000278-2	A C I BLOWPAK VICTORIA (Australia)	44	20/04/2004
Active	MI-20042004-LI-000278-2	A C I BLOWPAK VICTORIA (Australia)	44	20/04/2004
Active	MI-20042004-LI-000278-2	A C I BLOWPAK VICTORIA (Australia)	44	20/04/2004
Active	MI-20042004-LI-000278-2	A C I BLOWPAK VICTORIA (Australia)	44	20/04/2004
Submitted	MI-20042004-LI-000278-2	A C I BLOWPAK VICTORIA (Australia)	44	20/04/2004
Submitted	MI-05052004-LI-000438-2	WILLIAM PEARCE & CO P/L (Australia)	34-38B MCEVOY ST	05/05/2004
Submitted	MI-20042004-LI-000278-2	A C I BLOWPAK VICTORIA (Australia)	44	20/04/2004
Submitted	MI-20042004-LI-000278-2	A C I BLOWPAK VICTORIA (Australia)	44	20/04/2004
Active	MI-20042004-LI-000278-2	A C I BLOWPAK VICTORIA (Australia)	44	20/04/2004
Submitted	MI-04052004-LI-000426-2	WILLIAM PEARCE & CO P/L (Australia)	34-38B MCEVOY ST	04/05/2004
Under Review	MI-04052004-LI-000424-2	FRA PRODUCTION (Italy)	FRAZ S MATTEO RONDO 38	04/05/2004

Fig. 16. View Submitted Licence Applications List

Submitted Licence List

This screen lists all of the licence applications submitted to the TGA for processing. Clicking on the status will open that application.

Read Only Fields

Status (Pg 100) shows the current status of the application. This will change as the application is processed and finalised by the TGA.

Tracking Number is created by the system once the application has been saved or submitted. It is a unique number which is attached to the application and is used for all future tracking of the application through the system.

Manufacturer's Name is the name of the manufacturer associated with the application.

Primary Street Address is the first line of the primary site's address.

Received is the date the application was received by the TGA after being submitted.

Fig. 17. View Submitted Licence Application

**Submitted
Licence
Application**

This form is used to view an application that has been submitted. No changes can be made to the application. If changes are required, the application must be withdrawn and a new draft copy created.

**Read Only
Fields**

Applicant's Own Ref is the applicant's own reference information that may be useful in the client's identification of their application.

Status (Pg 100) is the current status of the application within the system.

Tracking Number is created by the system once the application has been saved or submitted. It is a unique number which is attached to the application and is used for all future tracking of the application through the system.

The following field is only displayed when viewing a **variation**.

Original Tracking Number is the tracking number of the original application.

Other

Client Details, Primary Site, Secondary Site and Supporting Documents are as per **New Licence Application** but cannot be edited.

Fees and Payments is covered in the next section.

The screenshot shows a web browser window titled "Licence Application - Microsoft Internet Explorer provided by Health". The address bar shows a URL from the TGA SIME system. The page header includes the TGA logo and "THERAPEUTIC GOODS ADMINISTRATION". Below the header, there's a "SIME Licence Application" section with navigation buttons: "Close", "View Entire App", "Withdraw", "New Draft Copy", and "Home".

Application details are listed:

- Applicant's Own Ref: [text box]
- Status: Submitted
- Tracking Number: MI-29042004-LI-000382-2
- Original Tracking Number: MI-20042004-LI-000278-2

The "Migrated Record Application" section has tabs for "Client Details", "Primary Site", "Secondary Site", "Supporting Documents", and "Fees and Payments". The "Fees and Payment" tab is active, showing a table with the following data:

Fees and Payment	
Fee:	\$0.00
Payment Type:	Visa

The bottom of the browser window shows a status message "Application loaded successfully." and a taskbar with various open applications.

Fig. 18. Submitted Application – Fees & Payments

Fees & Payments

This form displays the fees and payments information for a submitted application.

Read Only Fields

Fee is the amount due or paid for the application.

Payment Type is the method of payment.

View Approved Licences

Licence Number	Manufacturers Name	Received	Approved
MI-20042004-LI-000278-2	A C I BLOWPAK VICTORIA (Australia)	20/04/2004	20/04/2004
MI-13052004-LI-000011-1	ROCHE COLORADO CORPORATION	20/04/2004	20/04/2004
MI-13052004-LI-000012-1	HOE HIN PAK FAH YEOW MANUFA	20/04/2004	20/04/2004
MI-13052004-LI-000016-1	FERROSAN AS	20/04/2004	20/04/2004
MI-13052004-LI-000018-1	SMITHKLINE BEECHAM (DUNGARV	20/04/2004	20/04/2004
MI-13052004-LI-000019-1	ETHICON ENDO-SURGERY INC	20/04/2004	20/04/2004
MI-13052004-LI-000020-1	ETHICON ENDO-SURGERY INC	20/04/2004	20/04/2004
MI-13052004-LI-000021-1	ETHICON ENDO-SURGERY INC	20/04/2004	20/04/2004
MI-13052004-LI-000022-1	ETHICON ENDO-SURGERY INC	20/04/2004	20/04/2004
MI-13052004-LI-000023-1	ETHICON ENDO-SURGERY INC	20/04/2004	20/04/2004
MI-13052004-LI-000024-1	ETHICON ENDO-SURGERY INC	20/04/2004	20/04/2004
MI-13052004-LI-000025-1	ENDOTEC	20/04/2004	20/04/2004
MI-13052004-LI-000028-1	MEDICAP LTD	20/04/2004	20/04/2004
MI-13052004-LI-000029-1	BECTON DICKINSON MED PRODUC	20/04/2004	20/04/2004
MI-13052004-LI-000032-1	BECTON DICKINSON MED PRODUC	20/04/2004	20/04/2004

Fig. 19. Approved Licences List

Approved Licences List

This screen lists all the licence applications submitted by the client and approved by the TGA. Clicking on the licence number will open that licence's details.

Read Only Fields

Licence Number is the tracking number that was allocated by the system when the application was created. It is a unique number which is attached to the application and is used for all future tracking of the application through the system.

Manufacturer's Name is the name of the manufacturer associated with the application.

Received is the date the application was received.

Approved is the date the application was approved.

Fig. 20. Approved Licence

Approved Licence

This form is used to view an application that has been approved. No changes can be made but, if changes are required, a variation application can be created.

Read Only Fields

Applicant's Own Ref is the applicant's own reference information that may be useful in the client's identification of their application.

Status (Pg 100) shows the current status of the application.

Tracking Number is created by the system once the application has been saved or submitted. It is a unique number which is attached to the application and is used for all future tracking of the application through the system. Once an application is approved, it becomes the licence number.

The following field is only displayed when viewing a **variation**.

Original Tracking Number is the tracking number of the original application.

Other

Client Details, Primary Site, Secondary Site and Supporting Documents are as per **New Licence Application** but cannot be edited.

Create Declaration

Declaration - Microsoft Internet Explorer provided by Health

File Edit View Favorites Tools Help

Back Forward Stop Refresh Home Search Favorites History Mail Print Edit

Address <http://tgacbr02/SIME/MIS/lodge.nsf/Declaration?OpenForm> Go Links

TGA THERAPEUTIC GOODS ADMINISTRATION

SIME Declaration Help

Print Preview Home

Certification in Relation to Persons Involved with the Applicant for a Licence to Manufacture Therapeutic Goods and Other Persons - Australian Manufacture.

I, A Valued Client hold the position of Chairman in [Please enter the name of your company] at [Please enter your address] understand that the certification below is made for the purpose of assisting the Secretary of the Commonwealth Department of Health and Ageing or her delegate to consider whether the applicant

I/ A Valued Client or a licence to manufacture therapeutic goods the Applicant), persons who participate in, or are likely to participate in, managing the Applicant's affairs (Applicant Managers) and persons who have, or are likely to have, effective control over the Applicant (Applicant Controllers) are fit and proper persons for the purposes of section 38 of the Therapeutic Goods Act 1989, an extract of which is attached.

I hereby certify that:

(a) there has been no suspension or revocation of a manufacturing licence or conformity assessment certificate (however described) issued to the Applicant, any Applicant Manager or Applicant Controller, any other person who controls the Applicant or any Applicant Manager or Applicant Controller (either directly or indirectly through one or more interposed entities) or any person whom the Applicant or any Applicant Manager or Applicant Controller controlled (either directly or indirectly through one or more interposed entities) at the time of the suspension or revocation;

(b) there has been no conviction for an offence against a law of the Commonwealth, a State or Territory against the Applicant or any Applicant Manager or Applicant Controller, or other person who controls the Applicant or the Applicant Manager or Applicant Controller (either directly or indirectly through one or more interposed entities) or any person whom the Applicant or Applicant Manager or Applicant Controller controlled (either directly or indirectly through one or more interposed entities) at the time the offence was committed or the time of the conviction; (c) there has been no failure to comply with a condition of a manufacturing licence or conformity assessment certificate (however described) by the Applicant or any other person who controls the Applicant or Applicant Manager or Applicant Controller (either directly or indirectly through one or more interposed entities) or any person whom the Applicant or I controlled (either directly or indirectly through one or more interposed entities) at the time of the failure.

Optional further information

I wish to volunteer the following information about the applicant or other persons to assist the Secretary in determining the application for a licence to manufacture therapeutic goods.

I hereby declare that the above information, is true and correct:

Signature	Witnessed by
Date	Signature
	Date

Note: Giving false or misleading information is a serious offence

Start | Workspace - Lotus ... | Declaration - Mi... | Exploring - User Do... | Microsoft Word - Sl... | untitled - Paint | Local intranet | 10:05

Fig. 21. Create Declaration Form

Create Declaration

This form is used to create a declaration for a licence to manufacture therapeutic goods. The form must, after completion, be printed, signed and one copy sent to TGA.

Editable Fields *Applicant's Name.* Name of person making the application. To be entered in two places.

Position. The position of the applicant in the company.

Company Name. Name of the company.

Applicant's Address. Company's address.

Optional Further Information. Any additional information that relates to the application.

Overseas Manufacturer Certification

Certification Application Processing

Draft Applications

To create a new certification application :-

- 1) Click on *Create New Certification Application* on the Manufacturers Application Lodgement home page (Pg 10).
- 2) A new application entry form will be opened (Pg 48). Enter the *Applicant's Own Reference* information if required.
- 3) Enter the *Client Details* (Pg 50), *Primary Site* (Pg 52) and *Supporting Documents* (Pg 55) as described below.
- 4) Save the application as a draft copy by clicking on the "Save" button.

To edit an existing draft certification application :-

- 1) Click on *View Draft Certifications* on the Manufacturers Application Lodgement home page (Pg 10).
- 2) A list of all the draft applications currently in the system will be displayed (Pg 60). To view the application, click on its *Tracking Number*. If the number of applications exceeds the page size, use the "Previous" and "Next" buttons to page backwards and forwards. Alternatively, search for the required application using the "Search" button.
- 3) Once the application has been displayed, it can be changed by clicking on the "Edit" button (Pg 61). The application will be opened in edit mode and the changes can be made.
- 4) Save the changes by clicking on the "Save" button.

To input the application details :-

- 1) The application form is divided into a number of individual pages. When first displaying the form, the *Client Details* page is shown (Pg 50).
- 2) Clicking on the other page buttons will open them for editing. The other individual pages include *Primary Site* (Pg 52) and *Supporting Documents* (Pg 55).
- 3) All fields marked with a red star are mandatory and must be entered.

To view and print an application :-

- 1) To view the entire application, click on "View Entire App". A new window will open which shows the full application in "printer friendly" view.
- 2) Clicking on "Print" will print out the full application.

Draft Applications (continued)To save, save and close or to exit without saving :-

- 1) To save an application without exiting, click on “Save”. Clicking on “Close” will also save the application but will then exit to the Manufacturers Application Lodgement home page.
- 2) To exit without saving any changes made to the currently displayed page, click on “Home”. Control will be returned to the Manufacturers Application Lodgement home page.

To validate an application :-

- 1) Once all the data has been entered into the form, the application should be validated by clicking on “Validate”.
- 2) Any errors will be listed on the screen via a dialog box. Clicking on an error displays the corresponding place in the application so that it can be corrected.
- 3) All applications must pass validation successfully before they can be submitted.

ApplicationsTo submit an application :-

- 1) To submit an application, you must be in “edit” mode. Click on the “Submit” button.
- 2) All applications are automatically validated and, if errors are found, a dialog box will be displayed listing the errors. Clicking on an error will position the application in the appropriate place so that it can be corrected.
- 3) When submitting an application, a dialog box appears requesting a further two steps be actioned (Pg 62) as follows:
 - *Step 1 - Fees and Payments* (Pg 63).
 - *Step 2 - Tax Invoice* (Pg 64).Click on the “Continue” button to continue.
- 4) *Fees and Payments* (Pg 63). The cost of the application is displayed and an option to select a method of payment. If the cheque option is taken, then the cheque number and the bank must be entered.
- 5) *Tax Invoice* (Pg 64). A tax invoice is displayed with details taken from the application. It must be checked to ensure it is correct. After clicking on “Next”, a “printer friendly” version is displayed which can be printed by clicking on “Print”. A copy of the printed tax invoice must be faxed to TGA. Credit card details will have to be filled in if paying by credit card.
- 6) Click on “Finish” to complete the submission.

To view the progress of a submission :-

- 1) Click on *View Submitted Certification Applications* on the Manufacturers Application Lodgement home page (Pg 10).

**Applications
(continued)**

- 2) A list of all the submitted applications currently in the system will be displayed (Pg 65). The first column is the applications status code (Pg 100) which indicates the progress of the application. To view the application, click on its *Status* (Pg 66). If the number of applications exceeds the page size, use the “Previous” and “Next” buttons to page backwards and forwards. Alternatively, search for the required application using the “Search” button. An application in submission status cannot be changed. It can however, be withdrawn and a new application made.
- 3) Clicking on “New Draft Copy” will result in a new draft application being created with the details initialised to the values in the current application.

To withdraw an application :-

- 1) Click on *View Submitted Certification Applications* on the Manufacturers Application Lodgement home page (Pg 10).
- 2) A list of all the submitted applications currently in the system will be displayed (Pg 65). The first column is the applications status (Pg 100) which indicates the progress of the application. To view the application, click on its *Status* (Pg 66). Click on “Withdraw” to withdraw the application.
- 3) A dialog box will pop up asking for confirmation of the withdrawal. Click on “OK” to continue.
- 4) The status of the application will be changed to Pending Withdrawal (Pg 100).

**Approved
Certifications**To view an approved certification :-

- 1) Click on *View Approved Certifications* on the Manufacturers Application Lodgement home page (Pg 10). Alternatively, click on *View All TGA Data* (Pg 97) then select “Certifications”.
- 2) A list of all the approved certifications currently in the system and owned by the user, will be displayed (Pg 68). To view the certification, click on its *Certification Number* (Tracking Number) (Pg 69). If the number of certifications exceeds the page size, use the “Previous” and “Next” buttons to page backwards and forwards. Alternatively, search for the required certification using the “Search” button.

To vary a certification :-

- 1) Approved certifications cannot be changed. They can however, have their status changed by clicking on “Vary Application”. This option is used Suspend or Cancel a certification. A new draft application is created which, when finalised by the TGA, will result in the requested status change (Pg 100).

**Approved
Certifications
(continued)**

- 2) Click on *View Approved Certifications* on the Manufacturers Application Lodgement home page (Pg 10). Alternatively, click on *View All TGA Data* (Pg 97) then select “Certifications”.
 - 3) A list of all the approved certifications currently in the system and owned by the user, will be displayed (Pg 68). To view the certification, click on its *Certification Number* (Tracking Number) (Pg 69).
 - 4) A new application will be created by clicking on “Vary Application”. The new application, once finalised by the TGA, will cause the details to be updated on the Certification. If you want to create a brand new application based on the same details of the current record, then use the “New Draft Copy” option.
-

New Certification Application

Fig. 22. New Certification Application

Application Details

This form is used to complete a new certification application or a variation application for an existing approved certification.

Read Only Fields

Status is always “Draft” (Pg 100).

Tracking Number is created by the system once the application has been saved or submitted. It is a unique number which is attached to the application and is used for all future tracking of the application through the system.

The following fields are only displayed when creating a **variation**.

Current Tracking Number is the tracking number of the original application.

New Tracking Number is the new tracking number created for this variation application.

Editable Fields The following fields are editable when creating an application or editing an existing draft application. These fields become non-editable once the application has been submitted.

Applicant's Own Ref is an editable field in which the applicant can place any reference information that will help them to identify the application.

Other *Client Details, Primary Site, Supporting Documents* and *Status* (Pg 100) are covered in the next sections.

New Certification Application - Microsoft Internet Explorer provided by Health

File Edit View Favorites Tools Help

Back Forward Stop Refresh Home Search Favorites History Mail Print Edit

Address <http://tgacbr02/SIME/MIS/lodge.nsf/Entry?OpenForm&Type=CE!> Go Links

Client Details Primary Site Supporting Documents

Applicant

Applicant Name: Valued Client

Client Id: 9999999

★ Address: PO Box 1234

Suburb: Melbourne State: VIC

Postcode: 3000 Country: Australia

Phone: Fax:

★ Email:

☐ Existing Manufacturer ☒ New Manufacturer

New Manufacturer

★ Client Name:

★ Address:

★ Suburb: State:

★ Postcode: Country: Australia

Application loaded successfully.

Local intranet

Start Workspace - L... New Certific... Exploring - User... Microsoft Word... 016_SIME_MI... 10:49

Fig. 23. Certification Application – Client Details

Client Details This form is used to input the client details.

Read Only Fields *Applicant's Name* is the name associated with the user currently signed in.

Client Id is the id of the applicant as recorded in TGA's Client System.

Suburb, State, Post Code, Phone & Fax are the remaining address details associated with the first line of address that was selected.

Editable Fields *Address* is the first line of the applicant's address associated with the user currently signed in. If there is more than one address, a drop down list is displayed so that the correct one can be selected.

Email is the applicant's email address.

Manufacturer Indicator is a radio button selection to indicate whether the manufacturer has already been registered with the TGA or is new.

**Editable Fields
(continued)****Existing manufacturer :-**

Search is a facility to search on all or part of the manufacturer's name. A separate dialog box pops up in which the search criteria can be entered. A list of matches are then displayed from where the required manufacturer can be selected.

Client Id is the client number of the manufacturer selected.

New Manufacturer :-

Client Name is the name of the manufacturer.

Address, Suburb, State, Post Code & Country are the address details of the manufacturer.

Fig. 24. Certification Application – Primary Site

Primary Site This form is used to input the primary site details.

Read Only Fields **Existing Site :-**

Suburb, State, Post Code & Country are the remaining address details associated with the first line of address that was selected.

Editable Fields Primary Site Details :-

Site Indicator is a radio button selection to indicate whether the site has already been registered for this manufacturer or is new.

Existing Site :-

Street Address is the first line of the primary address. If there is more than one address available, a drop down list is displayed so that the correct one can be selected.

New Site :-

Street Address, Suburb, State, Post Code & Country are the address details of the primary site.

Contact Details :-

Contact Name is the name of the contact person.

Phone, Fax & Mobile are the contact details of the contact person.

Email is the contact person's email address.

Quality Control is the name of the person in charge of quality control.

CV Attachment is the CV of the person in charge of quality control. An *Add Attachment* button is displayed which brings up a dialog box whereby the CV can be browsed and attached. A *Remove Attachment* button is also displayed which removes the attachment. Clicking on the CV will open it in a new window.

Production is the name of the person in charge of production.

CV Attachment is the CV of the person in charge of quality control. An *Add Attachment* button is displayed which brings up a dialog box whereby the CV can be browsed and attached. A *Remove Attachment* button is also displayed which removes the attachment. Clicking on the CV will open it in a new window.

Authorised For Release is the name of the person who is authorised to release.

**Editable Fields Manufacturing Items (Pg 99) :-
(continued)**

Add is a button which, when clicked on, brings up a dialog box to enter the manufacturing item details. Fields displayed are *Manufacturing Type*, *Sterility*, *Manufacturing Class*, *Dosage Form*, *Product Category* & *Manufacturing Step*. All fields can be populated from the drop down list or, if it is a new item, by typing in the details. The *Manufacturing Type* selected refines what values are permitted for the remaining entries. At least one *Manufacturing Item* must be entered.

Remove is a button which, when clicked, will remove unwanted items. Each item listed has a checkbox in front of it which must be clicked first. All items with a clicked checkbox are removed.

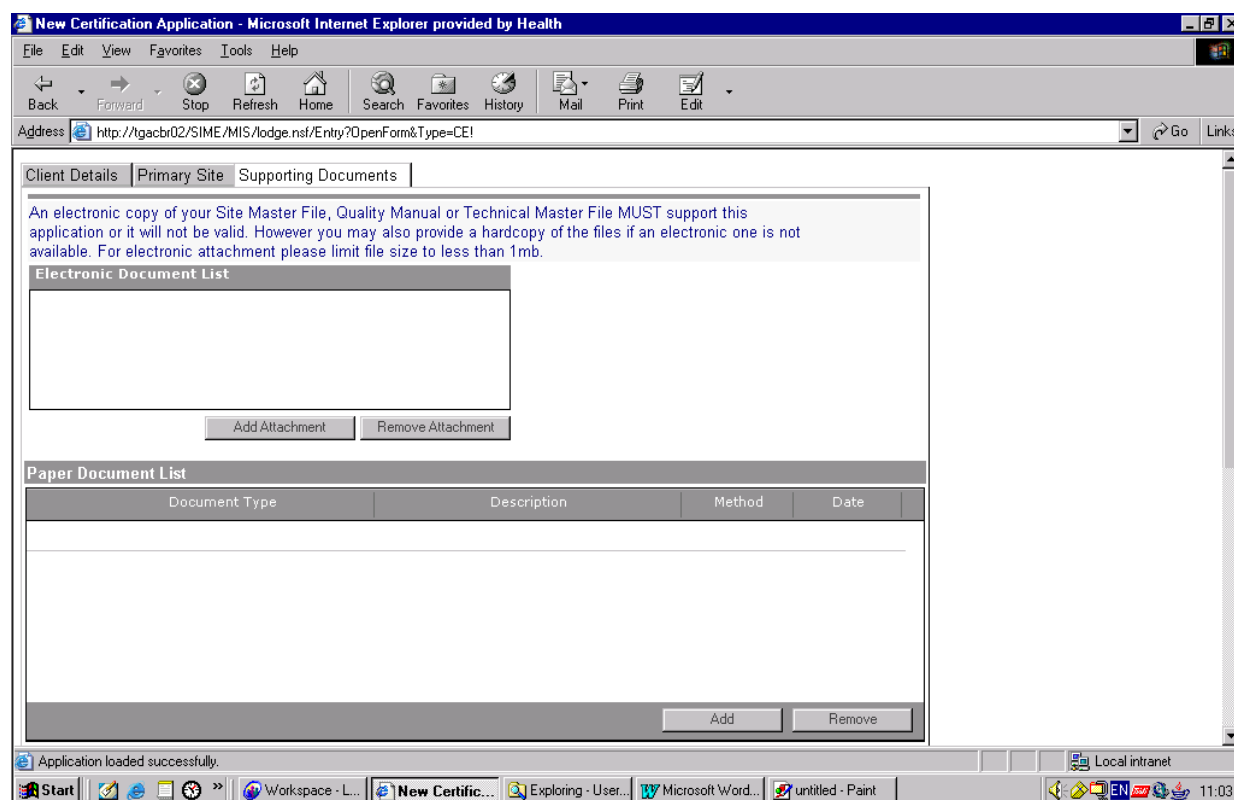


Fig. 25. Certification Application – Supporting Documents

Supporting Documents

This form is used to attach the supporting documents in support of the Certification application.

Editable Fields**Electronic Document List :-**

Add Attachment is a button which, when clicked on, brings up a dialog box whereby the document can be browsed and attached. At least one electronic or paper document (see below) must be entered. Clicking on a document will open the document in a new window.

Remove Attachment is a button which, when clicked on, can be used to remove unwanted attachments. Each attachment listed has a checkbox in front of it which must be clicked first. All attachments with a clicked checkbox are removed.

Editable Fields Paper Document List :-
(continued)

Add is a button which, when clicked on, brings up a dialog box whereby the document details can be entered. Fields displayed are *Document Type*, *Description*, *Method of Submission* & *Date Sent*. All fields are mandatory. *Document Type* can be selected from a drop down list or typed in. *Method of Submission* is selected by choosing one of the available radio buttons (Fax/Post/Courier). A convenient click on calendar has been included in the dialog box for *Date Sent*. At least one electronic (see above) or paper document must be entered.

Remove is a button which, when clicked on, can be used to remove unwanted entries. Each entry listed has a checkbox in front of it which must be clicked first. All entries with a clicked checkbox are removed.

The screenshot shows a web browser window titled "Variation: Licence Application - Microsoft Internet Explorer provided by Health". The address bar shows a URL from the SIME/MIS system. The page header includes the TGA logo and the text "TGA THERAPEUTIC GOODS ADMINISTRATION". Below the header, the page title is "Variation: Certification Application". There are buttons for "Save", "Close", "Validate", "Delete", "Submit", and "Home". The form displays the following information:

- Applicant's Ref: 1234
- Status: Draft
- Current Tracking Number: MI-07062004-CE-000145-2
- New Tracking Number: MI-24062004-CE-000150-2

Below this information is a link labeled "[x] Change Status". Underneath, there are two tabs: "Client Details" and "Status". The "Status" tab is active, showing a "Select new status:" section with two radio buttons: "Suspend" (selected) and "Cancel". Below this is a "Description:" label followed by a large text input area.

The status bar at the bottom of the browser window shows "Variation loaded successfully." and a taskbar with various open applications.

Fig. 26. Certification Application – Status

Status This form is used to request a change in status to an existing approved certification.

Editable Fields *Select New Status* (Pg 100) is a radio button option to select the action that is required for the application.

Description is a general comment as to why the change in status is required and any additional information that may be relevant.

Variation Certification Application

Variation.Licence Application - Microsoft Internet Explorer provided by Health

File Edit View Favorites Tools Help

Back Forward Stop Refresh Home Search Favorites History Mail Print Edit

Address <http://tgaabr02/SIME/MIS/lodge.nsf/0/FC97D956296A036ECA256ECF00012E78?E&Document> Go Links

TGA THERAPEUTIC GOODS ADMINISTRATION

SIME Variation: Certification Application Help

Save Close Validate Delete Submit Home

Applicant's Ref: 1234
 Status: Draft
 Current Tracking Number: MI-07062004-CE-000145-2
 New Tracking Number: MI-12072004-CE-000155-2

[\[x\] Change Status](#)

Client Details Status

Applicant Details

Applicant Name: Valued Client
 Client Id: 9999999
 Address: PO Box 1234
 Suburb: Melbourne State: VIC
 Postcode: 3000 Country: Australia
 Phone: Fax:
 Email: Staff@email.com

Manufacturer Details

Current Manufacturer

Variation loaded successfully.

Start Workspace - Lotus ... Exploring - DEAL Tra... Microsoft Word - SI... Variation: Licenc... untitled.bmp - Paint Local intranet 10:13

Fig. 27. Variation Application

Application Details

This form is used to create a variation certification application.

Read Only Fields

Status is always “Draft” (Pg 100).

Current Tracking Number is the tracking number of the original application.

New Tracking Number is the new tracking number created for this variation.

Editable fields

The following fields are editable when creating a variation. They become non-editable once the application has been submitted.

Applicant's Own Ref is an editable field in which the applicant can place any reference information that may help in identifying the application.

Change Details/Status Indicator (Pg 100) indicates to the system whether the variation is to change the details of the application to change its status.

Other

Client Details, Primary Site, Supporting Documents and Status (Pg 100) are as per **New Certification Application**.

View Draft Certification Applications

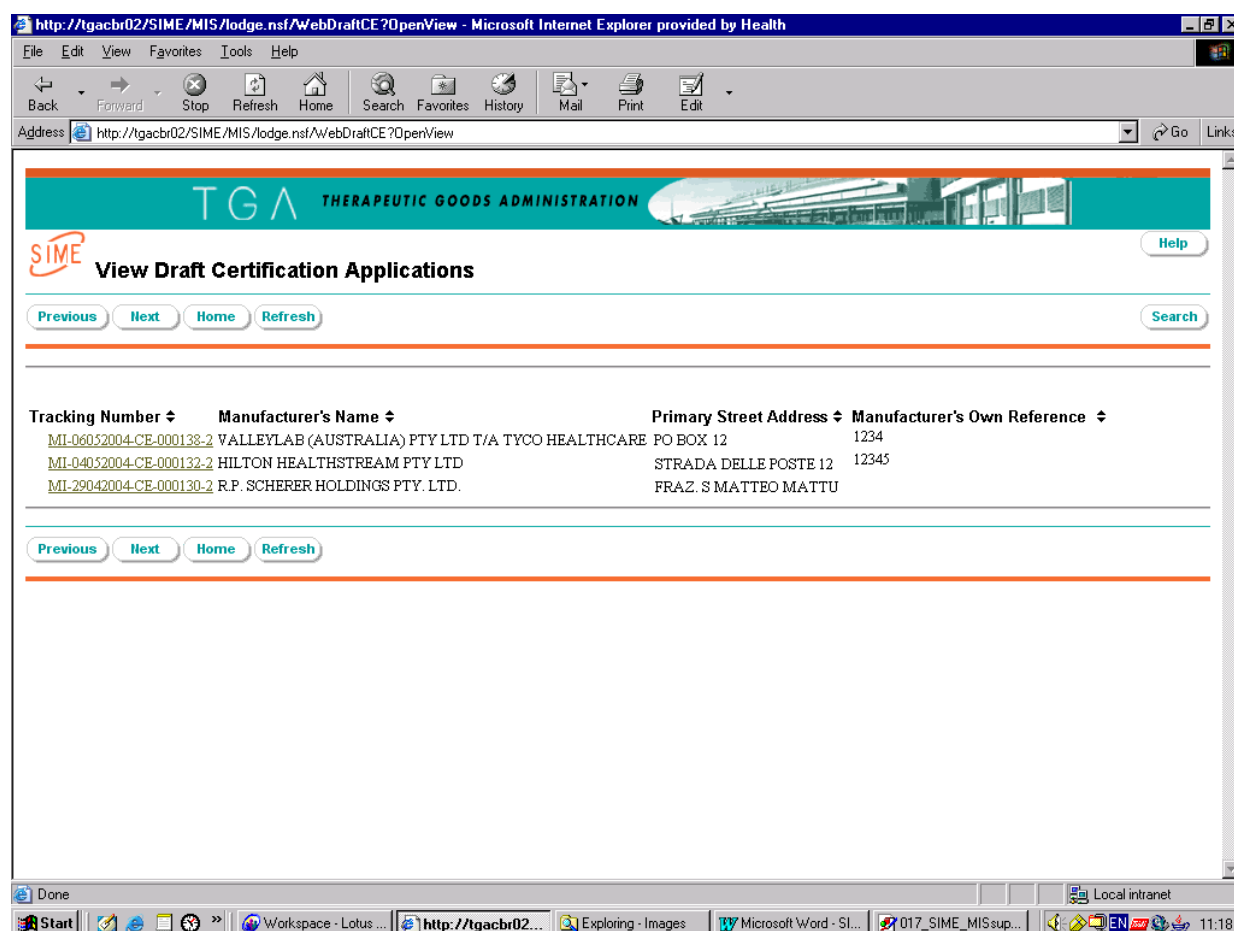


Fig. 28. View Draft Certifications List

Draft Certification List

This screen lists all the draft certification applications created by the user currently logged in. Clicking on a tracking number will open that application.

Read Only Fields

Tracking Number is created by the system once the application has been saved or submitted. It is a unique number which is attached to the application and is used for all future tracking of the application through the system.

Manufacturer's Name is the name of the manufacturer associated with the application.

Primary Street Address is the first line of the primary site's address.

Manufacturer's Own Reference is the applicant's reference information that helps identify the application.

Fig. 29. View Draft Certification Application

Draft Certification Application

This form is used to open an existing draft certification.

Read Only Fields

Status is always “Draft” (Pg 100).

Tracking Number is created by the system once the application has been saved or submitted. It is a unique number which is attached to the application and is used for all future tracking of the application through the system.

Editable fields

The following fields are editable when creating an application or editing an existing draft application. These fields become non-editable once the application has been submitted.

Applicant's Own Ref is an editable field in which the applicant can place any reference information that may help in identifying the application.

Other

Client Details, Primary Site, Supporting Documents and *Status* (Pg 100) are as per **New Certification Application**.

To Submit A Certification Application

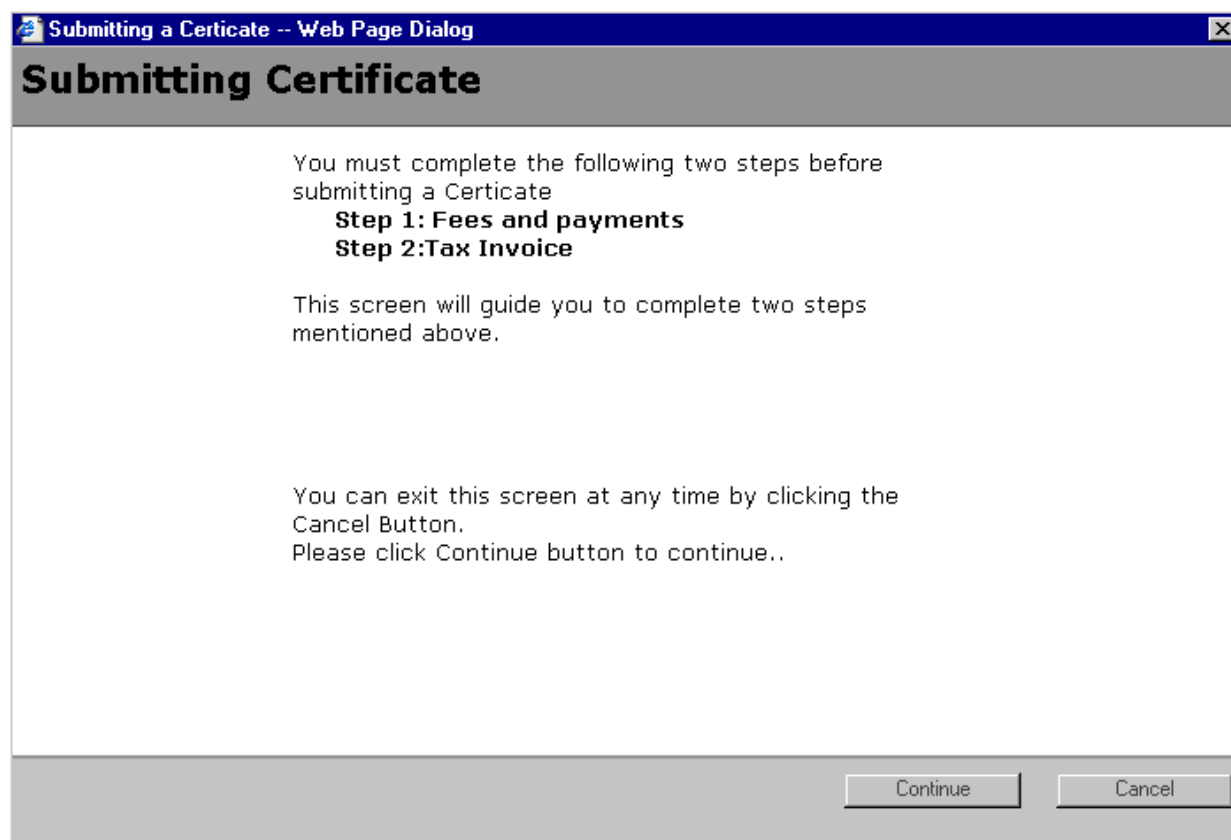


Fig. 30. Submitted Certification

Submitted Certification Steps

When submitting an application, a popup box appears requesting a further two steps be actioned as follows:

Step 1 - Fees and Payments

Step 2 - Tax Invoice

Submitting Certificate Fees and Payment

Fees: AUD \$100.20

★ Payment Type: ☒ Cheque ☐ Visa ☐ Bank Card ☐ Mastercard

★ Cheque No:

★ Bank:

Payable to: CEFinancial Services Group

Mail to: CEFinancial Services Group
Therapeutic Goods Administration
PO BOX 100
Woden ACT 2606
(02) 6232 8359
(02) 6232 8222

<< Previous Next >> Cancel

Fig. 31. Fees and Payments

Fees and Payments

All Certification applications are subject to a fee. This screen allows the user to nominate how payment will be made.

NOTE: If *Visa*, *Bank Card* or *Mastercard* is selected, the payment details must be entered on the *Tax Invoice* (see below). Card details are NOT kept on the system.

Read Only Fields

Fees contains the fee applicable for the type of application.

Payable/Mail To are the details of who the cheque must be made payable to and where to send it.

Editable Fields

Payment Type indicates the payment type. Values are Cheque, Visa, Bank Card & Mastercard.

Cheque No: (Only displayed if Payment Type is CHEQUE) Number of the cheque being sent as payment.

Bank: (Only displayed if Payment Type is CHEQUE) Editable field. Name of the bank the cheque has been drawn on.

Submitting Certificate Tax Invoice

Tax Invoice

This document will be a tax invoice for GST when you make payment. Please read the information below regarding your payment and ensure it is true and correct.

Application Details

Tracking Number: MI-04052004-CE-000132-2

Application For:

Applicant's Own Reference: 1265/23

Applicant's Details

Manufacturer Name: **Another Company Pty Ltd**

Manufacturer ID: **999995**

Contact Details:

Contact Name: **Valued Client**

Contact Email: **Staff@email.com**

Phone:

Fax:

<< Previous Next >> Cancel

Fig. 32. Tax Invoice

Tax Invoice This form is used to create a tax invoice for a certificate to manufacture therapeutic goods. The form must, after completion, be printed and one copy sent to TGA.

Read Only Fields *All Fields Except Card Details:* Populated from the contents of the application. This form is the *Tax Invoice for GST* once payment has been made. The details must be read to ensure it is correct. If not, the submission can be cancelled and the application changed to reflect the correct information. Submission can then be done again.

Card Details: (Only displayed if VISA, BANK CARD or MASTERCARD is selected as the Payment Type) Card information written on the printed version of the Tax Invoice will ONLY be used to make payment and is NOT retained in the system.

Card Holders Signature: After clicking *Next* on the *Tax Invoice* page, a "printer friendly" version is displayed which must be printed. The printed page must be faxed to TGA.

View Submitted Certification Applications

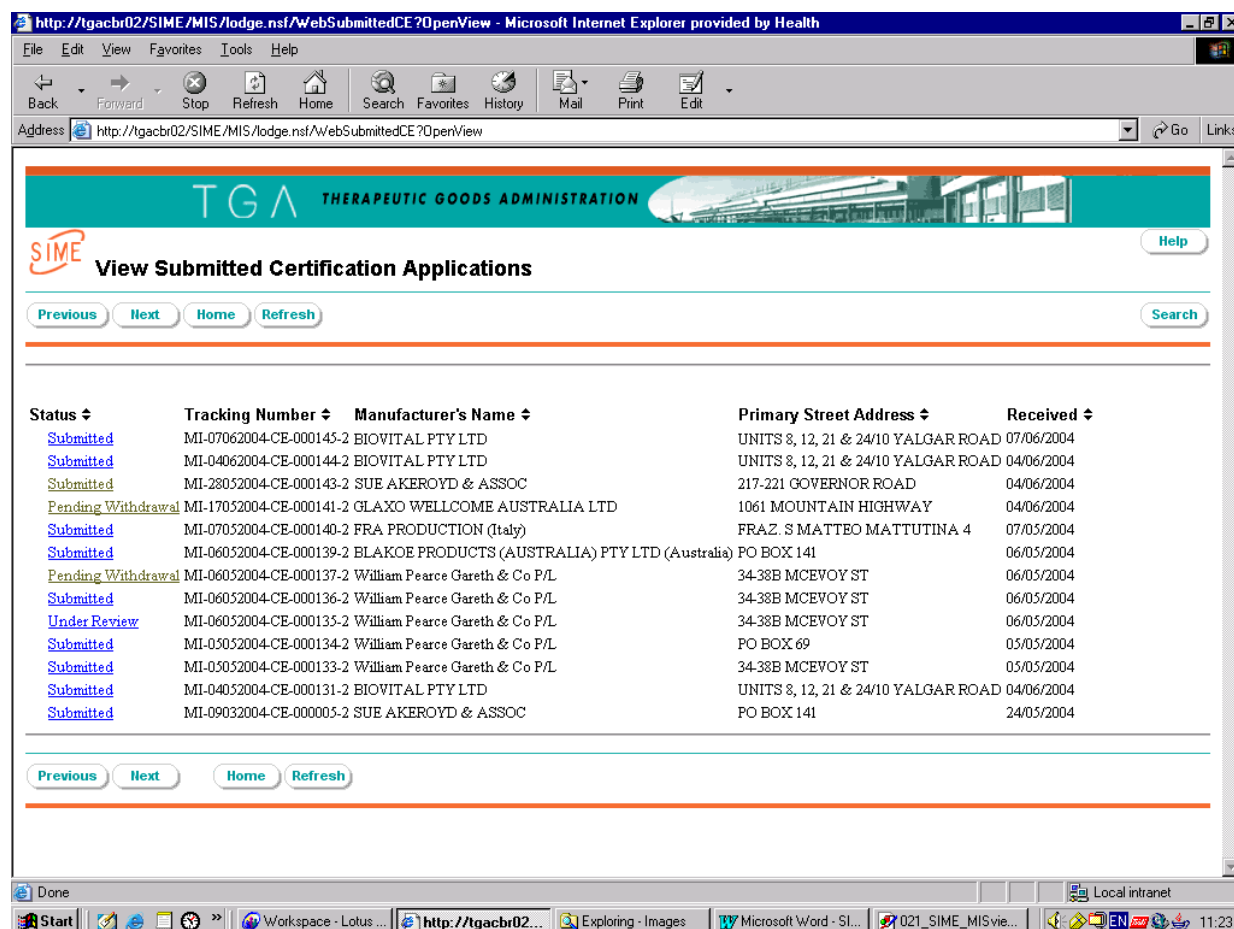


Fig. 33. View Submitted Certifications List

Submitted Certification List

This screen lists all the certification applications submitted by the user currently logged in and their status. Clicking on the status will open that application.

Read Only Fields

Status (Pg 100) shows the current status of the application.

Tracking Number is created by the system once the application has been saved or submitted. It is a unique number which is attached to the application and is used for all future tracking of the application through the system.

Manufacturer's Name is the name of the manufacturer associated with the application.

Primary Street Address is the first line of the primary site's address.

Received is the date the application was received.

Certification Application - Microsoft Internet Explorer provided by Health

File Edit View Favorites Tools Help

Back Forward Stop Refresh Home Search Favorites History Mail Print Edit

Address <http://tgacbr02/SIME/MIS/lodge.nsf/cb6363094271289bca256e3f007b0c2b/2319a66d76ca612ca256e8c0003cc60?OpenDocument> Go Links

TGA THERAPEUTIC GOODS ADMINISTRATION

SIME Certification Application Help

Close View Entire App Withdraw New Draft Copy Home

Applicant's Own Ref: 123456789
 Status: Submitted
 Tracking Number: MI-06052004-CE-000136-2

Client Details Primary Site Supporting Documents Fees and Payments

Applicant

Applicant Name: Valued Client
 Client Id: 9999999
 Address: PO Box 1234
 Suburb: Melbourne State: VIC
 Postcode: 3000 Country: Australia
 Phone: Fax:
 Email: Staff@email.com

☒ Existing Manufacturer ☐ New Manufacturer

Application loaded successfully.

Start Workspace - Lotus ... Certification Ap... Exploring - Images Microsoft Word - Sl... 022_SIME_MISubli... Local intranet 11:27

Fig. 34. View Submitted Certification Application

Submitted Certification Application

This form is used to view an application that has been submitted. No changes can be made to the application. If changes are required, the application must be withdrawn and a new draft copy created.

Read Only Fields

Applicant's Own Ref is the applicant's own reference information that may help in identifying the application.

Status (Pg 100) is the current status of the submission within the system.

Tracking Number is created by the system once the application has been saved or submitted. It is a unique number which is attached to the application and is used for all future tracking of the application through the system.

The following field is only displayed when viewing a **variation**.

Original Tracking Number is the tracking number of the original application.

Other

Client Details, *Primary Site* and *Supporting Documents* are as per **New Certification Application** but cannot be edited.

Fees and Payments is covered in the next section.

The screenshot shows a web browser window titled "Certification Application - Microsoft Internet Explorer provided by Health". The address bar displays a URL starting with "http://tgacbr02/SIME/MIS/lodge.nsf/". The page header includes the TGA logo and "THERAPEUTIC GOODS ADMINISTRATION". Below the header, the "SIME Certification Application" is displayed with navigation buttons: "Close", "View Entire App", "Withdraw", "New Draft Copy", and "Home".

Applicant's Own Ref:
Status: Submitted
Tracking Number: MI-06052004-CE-000136-2

Client Details | Primary Site | Supporting Documents | Fees and Payments

Fees and Payment	
Fee:	\$100.20
Payment Type:	Cheque

Application loaded successfully.

Taskbar: Start, Workspace - Lotus..., Certification Ap..., Exploring - Images, Microsoft Word - SI..., 023_SIME_MISsub..., Local intranet, 11:28

Fig. 35. Submitted Application – Fees & Payments

Fees & Payments

This form displays the fees and payments information relating to the application. It is only displayed while the application is in submit status.

Read Only Fields

Fee is the amount due or paid for the application.

Payment Type is the method of payment.

View Approved Certifications

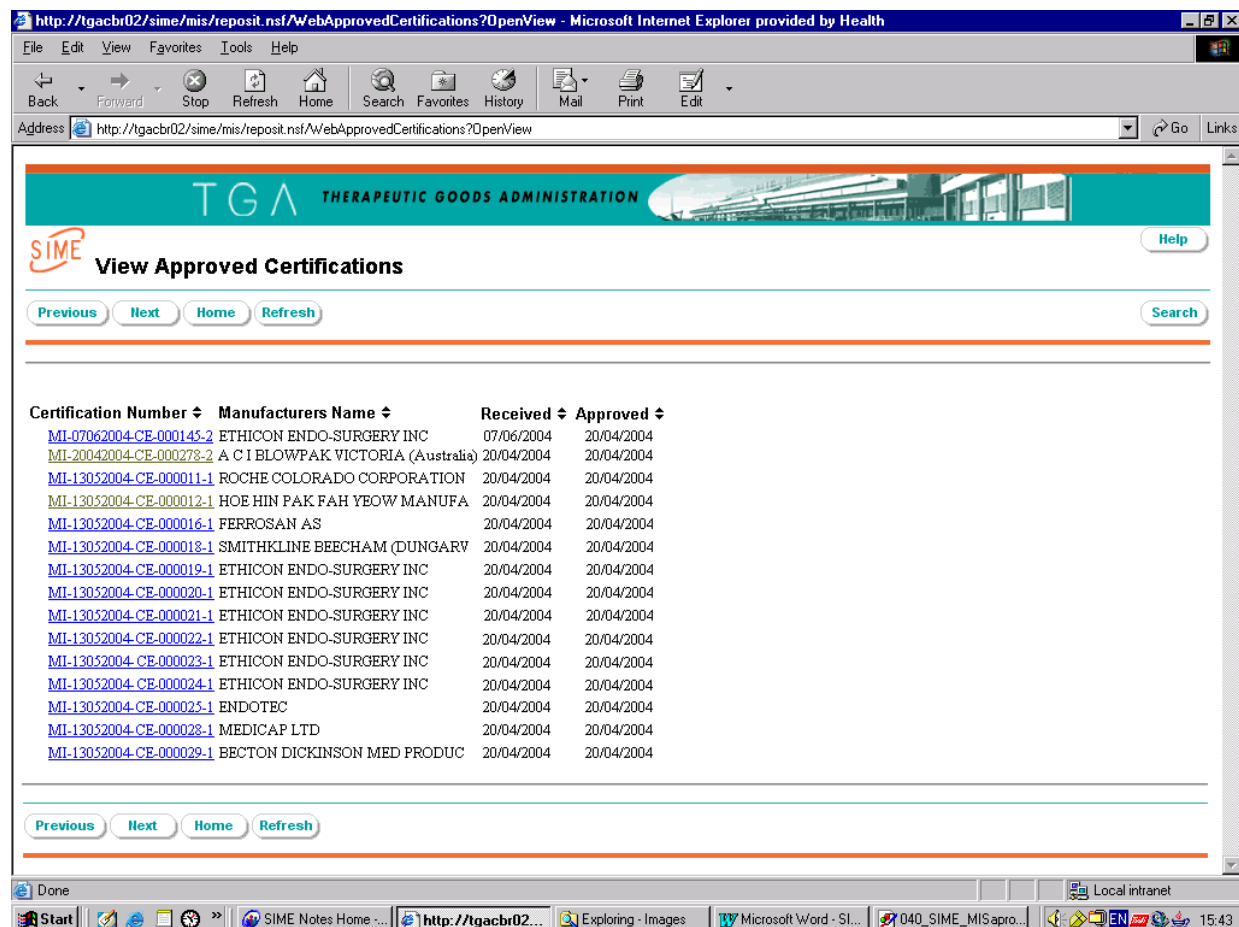


Fig. 36. Approved Certifications List

Approved Certifications List

This screen lists all the approved certifications owned by the user. Clicking on a certification number will open that certification for viewing.

Read Only Fields

Certification Number is the tracking number that was allocated by the system when the application was created. It is a unique number which is attached to the application and is used for all future tracking of the application through the system.

Manufacturer's Name is the name of the manufacturer associated with the application.

Received is the date the application was received.

Approved is the date the application was approved.

Fig. 37. Approved Certification

Approved Certification

This form is used to view an approved certification. No changes can be made but, if changes are required, a variation application to the certification can be created.

Read Only Fields

Applicant's Own Ref is the applicant's own reference information that may help to identify the application.

Status (Pg 100) shows the current status of the application.

Tracking Number is created by the system once the application has been saved or submitted. It is a unique number which is attached to the application and is used for all future tracking of the application through the system. Once an application is approved, it becomes the certification number.

The following field is only displayed when viewing a **variation**.

Original Tracking Number is the tracking number of the original application.

Other

Client Details, Primary Site and *Supporting Documents* are as per **New Certification Application** but cannot be edited.

Overseas Manufacturer GMP Clearances

Clearance Application Processing

Draft Applications

To create a new clearance application :-

- 1) Click on *Create New Clearance Application* on the Manufacturers Application Lodgement home page (Pg 10).
- 2) A new application entry form will be opened (Pg 74). Enter the *Applicant's Own Reference* information if required.
- 3) Enter the *Client Details* (Pg 76), *Evidence* (Pg 79) and *API/Product Details* (Pg 81) as described below.
- 4) Save the application as a draft copy by clicking on the "Save" button.

To edit an existing draft clearance application :-

- 1) Click on *View Draft Clearances* on the Manufacturers Application Lodgement home page (Pg 10).
- 2) A list of all the draft applications currently in the system will be displayed (Pg 86). To view the application, click on its *Tracking Number* (Pg 87). If the number of applications exceeds the page size, use the "Previous" and "Next" buttons to page backwards and forwards. Alternatively, search for the required application using the "Search" button.
- 3) Once the application has been displayed, it can be changed by clicking on the "Edit" button. The application will be opened in edit mode and the changes can be made.
- 4) Save the changes by clicking on the "Save" button.

To input the application details :-

- 1) The application form is divided into a number of individual pages. When first displaying the form, the *Client Details* page is shown (Pg 76).
- 2) Clicking on the other page buttons will open them for editing. The other individual pages include *Evidence* (Pg 79) and *API/Product Details* (Pg 81).
- 3) All fields marked with a red star are mandatory and must be entered.

To view and print an application :-

- 1) To view the entire application, click on "View Entire App". A new window will open which shows the full application in a "printer friendly" view.
- 2) Clicking on "Print" will print out the full application.

Draft Applications (continued)To save, save and close or to exit without saving :-

- 1) To save an application without exiting, click on “Save”. Clicking on “Close” will also save the application but will then exit to the Manufacturers Application Lodgement home page.
- 2) To exit without saving any changes made to the currently displayed page, click on “Home”. Control will be returned to the Manufacturers Application Lodgement home page.

To validate an application :-

- 1) Once all the data has been entered into the form, the application should be validated by clicking on “Validate”.
- 2) Any errors will be listed on the screen via a dialog box. Clicking on an error displays the corresponding place in the application so that it can be corrected.
- 3) All applications must pass validation successfully before they can be submitted.

ApplicationsTo submit an application :-

- 1) To submit an application, you must be in “edit” mode. Click on the “Submit” button.
- 2) All applications are automatically validated and, if errors are found, a dialog box will be displayed listing the errors. Clicking on an error will position the application in the appropriate place so that it can be corrected.
- 3) When submitting an application, a dialog box appears (Pg 88) requesting a further two steps be actioned as follows:
 - *Step 1 - Fees and Payments* (Pg 89).
 - *Step 2 - Tax Invoice* (Pg 90).
 Click on the “Continue” button to continue.
- 4) *Fees and Payments* (Pg 89). The cost of the application is displayed and an option to select a method of payment. If the cheque option is taken, then the cheque number and the bank must be entered.
- 5) *Tax Invoice* (Pg 90). A tax invoice is displayed with details taken from the application. It must be checked to ensure it is correct. After clicking on “Next”, a “printer friendly” version is displayed which can be printed by clicking on “Print”. A copy of the printed tax invoice must be faxed to TGA. Credit card details will have to be filled in if paying by credit card.
- 6) Click on “Finish” to complete the submission.

To view the progress of an application :-

- 1) Click on *View Submitted Clearance Applications* on the Manufacturers Application Lodgement home page (Pg 10).

**Applications
(continued)**

- 2) A list of all the submitted applications currently in the system will be displayed (Pg 91). The first column is the applications status code (Pg 100) which indicates the progress of the application. To view the application, click on its *Status* (Pg 92). If the number of applications exceeds the page size, use the “Previous” and “Next” buttons to page backwards and forwards. Alternatively, search for the required application using the “Search” button. An application in submission status cannot be changed. It can however, be withdrawn and a new application made.
- 3) Clicking on “New Draft Copy” will result in a new draft application being created with the details initialised to the values in the current application.

To withdraw an application :-

- 1) Click on *View Submitted Clearance Applications* on the Manufacturers Application Lodgement home page (Pg 10).
- 2) A list of all the submitted applications currently in the system will be displayed (Pg 91). The first column is the applications status (Pg 100) which indicates the progress of the application. To view the application, click on its *Status* (Pg 92). Click on “Withdraw” to withdraw the application.
- 3) A dialog box will pop up asking for confirmation of the withdrawal. Click on “OK” to continue.
- 4) The status of the application will be changed to Pending Withdrawal (Pg 100).

**Approved
Clearances**To view an approved clearances :-

- 1) Click on *View Approved Clearances* on the Manufacturers Application Lodgement home page (Pg 10). Alternatively, click on *View All TGA Data* (Pg 97) then select “Clearances”.
- 2) A list of all the approved clearances currently in the system and owned by the user, will be displayed (Pg 95). To view the clearance, click on its *Clearance Number* (Tracking Number) (Pg 96). If the number of clearances exceeds the page size, use the “Previous” and “Next” buttons to page backwards and forwards. Alternatively, search for the required clearance using the “Search” button.

To vary a clearance :-

- 1) Approved clearances cannot be changed. They can however, have their status changed by clicking on “Vary Application”. This option is used Suspend, Cancel or Re-activate a clearance. A new draft application is created which, when finalised by the TGA, will result in the requested status change (Pg 100).
- 2) Click on *View Approved Clearances* on the Manufacturers Application Lodgement home page (Pg 10). Alternatively, click on *View All TGA Data* (Pg 97) then select “Clearances”.

**Approved
Clearances
(continued)**

- 3) A list of all the approved clearances currently in the system and owned by the user, will be displayed (Pg 95). To view the clearance, click on its *Clearance Number* (Tracking Number) (Pg 96).
 - 4) A new application will be created by clicking on “Vary Application”. The new application, once finalised by the TGA, will cause the details to be updated on the Clearance. If you want to create a brand new application based on the same details of the current record, then use the “New Draft Copy” option.
-

New Clearance Application

Fig. 38. New GMP Clearance Application

Application Details

This form is used to complete a new clearance application or a variation to an existing approved clearance.

Read Only Fields

Status is always “Draft” (Pg 100).

Tracking Number is created by the system once the application has been saved or submitted. It is a unique number which is attached to the application and is used for all future tracking of the application through the system.

The following fields are only displayed when creating a **variation**.

Current Tracking Number is the tracking number of the original application.

New Tracking Number is the new tracking number created for this variation.

Editable Fields The following fields are editable when creating an application or editing an existing draft application. These fields become non-editable once the application has been submitted.

Applicant's Own Ref is an editable field in which the applicant can place any reference information that may help to identify the application.

The following fields are only displayed when creating a **variation**.

Change Details/Status Indicator (Pg 100) indicates to the system whether the variation is to change the details of the application to change its status.

Other *Client Details, Evidence, API/Product* and *Status* (Pg 100) are covered in the next sections.

Client Details Evidence API/Product Details

Applicant

★ Applicant Name: Valued Client

★ Client Id: 9999999

★ Address: PO Box 1234

★ Suburb: Melbourne State: VIC

★ Postcode: 3000 Country: Australia

★ Phone: Fax:

★ Email:

Sponsor

★ Sponsor Name: Australian Company Pty Ltd

★ Client Id: 9999999

★ Address: Sunny Street

★ Suburb: Brisbane State: QLD

★ Postcode: 4000 Country: Australia

★ Phone: Fax:

★ Email:

Contact Details

★ Contact Name:

★ Phone: ★ Fax:

★ Mobile:

★ Email:

☐ Existing Manufacturer ☒ New Manufacturer

New Manufacturer

★ Client Name:

★ Address:

★ Suburb: ★ State:

★ Postcode: ★ Country: Australia

Fig. 39. Clearance Application – Client Details

Client Details This form is used to input the client details.

Read Only Fields **Applicant :-**

Applicant's Name is the name associated with the user currently logged in.

Client Id is the id of the applicant as recorded in the TGA's Client System.

Suburb, State, Post Code, Phone & Fax are the remaining address details associated with the first line of the address that was selected.

**Read Only
Fields****(continued)****Applicant :-**

Applicants Name is the name associated with the user currently signed in.

Client Id is the id of the applicant as recorded in the TGA's Client System.

Suburb, State, Post Code, Phone & Fax are the remaining address details associated with the first line of address that was selected.

Sponsor :-

Client Id is the id of the sponsor as recorded in the TGA's Client System.

Suburb, State, Post Code, Phone & Fax are the remaining address details associated with the first line of address that was selected.

Editable Fields**Applicant :-**

Address is the first line of the applicant's address associated with the user currently signed in. If there is more than one address associated, a drop down list is displayed so that the correct one can be selected.

Email is the applicant's email address.

Sponsor :-

Sponsor Name is the name of the sponsor of the application. The sponsor must be selected from a drop down list of possible sponsors.

Address is the first line of the sponsor's address. If there is more than one address associated, a drop down list is displayed so that the correct one can be selected.

Email is the sponsor's email address.

Contact :-

Contact Name is the name of the contact person.

Phone, Fax & Mobile are the contact details of the contact person.

Email is the contact person's email address.

Editable Fields
(continued)**Manufacturer :-**

Manufacturer Indicator is a radio button selection to indicate whether the manufacturer is currently registered with the TGA or is new.

Existing manufacturer :-

Search is a facility to search on all or part of the manufacturer's name. A separate dialog box pops up in which the search criteria can be entered. A list of matches are then displayed from where the required manufacturer can be selected.

Client Id is the client number of the manufacturer selected.

New Manufacturer :-

Manufacturer Name is the name of the manufacturer.

Site, Suburb, State, Post Code & Country are the address details of the manufacturer.

Fig. 40. Clearance Application – Evidence

Evidence This form is used to attach the evidence documents associated with the application.

Editable Fields *S31 Request* is a radio button selection which indicate whether or not the application is in response to a S31 request from the TGA.

S31 Reference Number (Only displayed if S31 Indicator is "YES"). To be completed with the number on the request received from the TGA.

Supporting Documents :-

Add Attachment is a button which, when clicked on, brings up a dialog box whereby the document can be browsed and attached. At least one electronic or paper document (see below) must be entered. Clicking on a document will open the document in a new window.

Remove Attachment is a button which, when clicked on, can be used to remove unwanted attachments. Each attachment listed has a checkbox in front of it which must be clicked first. All attachments with a clicked checkbox are removed.

**Editable Fields
(continued)**

Evidence Indicator is a radio button selection which indicates whether the evidence is provided by the applicant or whether the applicant is requesting that it be obtained by the TGA.

Evidence :-

Add is a button which, when clicked on, brings up a dialog box whereby the document details can be entered. Fields displayed are *Document Type*, *Document Number*, *Date Of Last Inspection & Document Expiry*. All fields are mandatory. *Document Type* can be selected from a drop down list or typed in. *Method of Submission* is selected by choosing one of the available radio buttons (Fax/Post/Courier). A convenient click on calendar has been included in the dialog box for *Date Sent*. At least one support (see above) or evidence document must be entered.

Remove is a button which, when clicked on, can be used to remove unwanted entries. Each entry listed has a checkbox in front of it which must be clicked first. All entries with a clicked checkbox are removed.

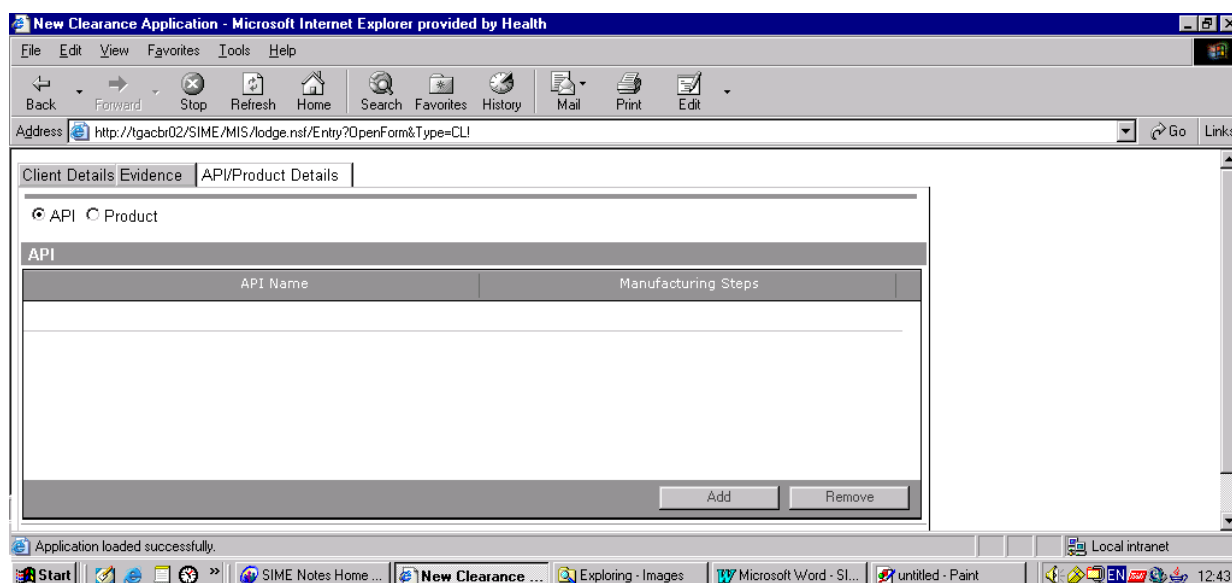


Fig. 41. Clearance Application – API/Product Details

**API/Product
Details**

This form is used to input the API or Product details associated with the clearance application.

Editable Fields *API/Product* is a radio button selection which indicates whether the details being provided are for an API or Product.

API :- (Only displayed if API/Product indicator is "API")

Add is a button which, when click on, brings up a dialog box whereby the API details can be entered. Fields displayed are *API Name & Manufacturing Step*. All fields are mandatory. *API Name* is an editable field that must be typed in. *Manufacturing Step* can be typed in or selected from a drop down list. At least one API must be entered.

Remove is a button which, when clicked on, can be used to remove unwanted entries. Each entry listed has a checkbox in front of it which must be clicked first. All entries with a clicked checkbox are removed.

Product Details :- (Only displayed if API/Product indicator is "Product")

Add is a button which, when clicked on, brings up a dialog box to enter the product details. Fields displayed are *Manufacturing Type, Sterility, Manufacturing Class, Dosage Form, Product Category & Manufacturing Step*. All fields can be populated from the drop down list or, if it is a new product, by typing in the details. The *Manufacturing Type* selected refines what values are permitted for the remaining entries. At least one API must be entered.

Remove is a button which, when clicked on, can be used to remove unwanted entries. Each entry listed has a checkbox in front of it which must be clicked first. All entries with a clicked checkbox are removed.

Microsoft Internet Explorer provided by Health

Address: http://tgacbr02/SIME/MIS/lodge.nsf/0/CA256DFD000019C4CA256EA80017D3267E?editDocument

TGA THERAPEUTIC GOODS ADMINISTRATION

Variation: Clearance Application [Help](#)

[Save](#) [Close](#) [Validate](#) [Delete](#) [Submit](#) [Home](#)

Applicant's Ref:

Status: Draft

Current Tracking Number: MI-13052004-CL-000012-1

New Tracking Number: MI-24062004-CL-000277-2

☐ Change Details ☒ Change Status

Client Details | **Status**

Select new status: ☒ Suspend ☐ Cancel ☐ Re-activate

Description:

Variation loaded successfully. Local intranet 14:54

Fig. 42. Clearance Application – Status

- Status** This form is used to request a change in status to an existing approved clearance.
- Editable Fields** *Select New Status* (Pg 100) is a radio button option to select the status that is required for the clearance.
- Description* is a general comment as to why the change to the status is required and any additional information that may be relevant.

Variation Clearance Application

Fig. 43. Variation Clearance Application

Application Details

This form is used to create a variation application on an existing approved clearance.

Read Only Fields

Status is always “Draft” (Pg 100).

Current Tracking Number is the tracking number of the original application.

New Tracking Number is the new tracking number created for this variation.

Editable fields

The following fields are editable when creating an application or editing an existing draft application. They become non-editable once the application has been submitted.

Applicant's Own Ref is an editable field in which the applicant can place any reference information that may help in identifying the application.

Change Details/Status Indicator (Pg 100) indicates to the system whether the variation is to change the details of the application to change its status.

Other

Client Details, Evidence, API/Product Details and Status (Pg 100) are as per
New Clearance Application.

View Draft GMP Clearance Applications

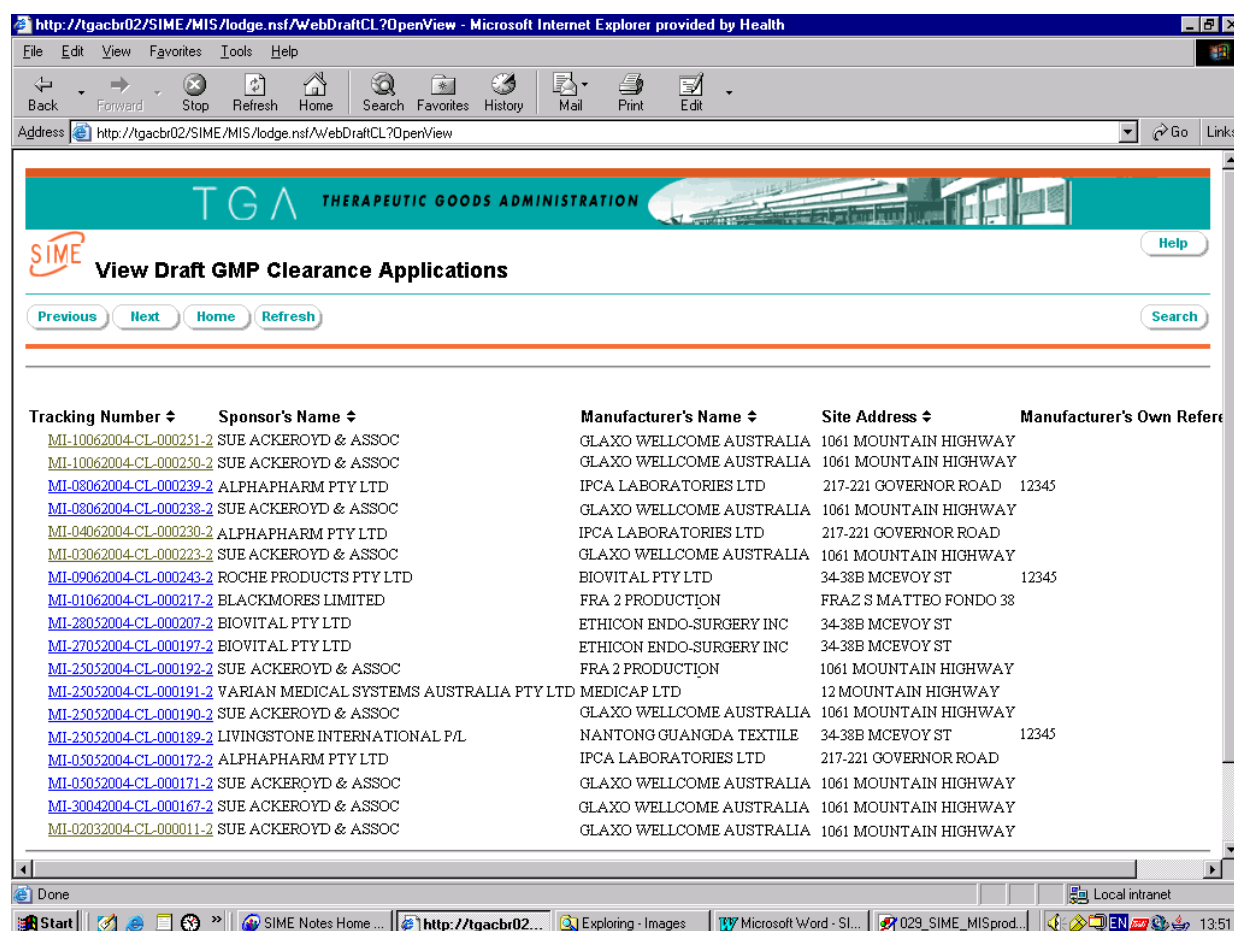


Fig. 44. View Draft GMP Clearances List

Draft Clearance List

This screen lists all the draft clearance applications owned by the user currently logged in. Clicking on a tracking number will open that application.

Read Only Fields

Tracking Number is created by the system once the application has been saved or submitted. It is a unique number which is attached to the application and is used for all future tracking of the application through the system.

Sponsor's Name is the name of the sponsor associated with the application.

Manufacturer's Name is the name of the manufacturer associated with the application.

Site Address is the first line of the primary site's address.

Manufacturer's Own Reference is the applicant's reference information that may help in identifying the application.

Clearance Application - Microsoft Internet Explorer provided by Health

File Edit View Favorites Tools Help

Back Forward Stop Refresh Home Search Favorites History Mail Print Edit

Address <http://tga.gov.au/SIME/MIS/lodge.nsf/d54a336932668f00ca256e3f00789197/5affd3bd681f5180ca256ea60007a20?OpenDocument> Go Links

TGA THERAPEUTIC GOODS ADMINISTRATION

SIME Clearance Application Help

Edit Close View Entire App New Draft Copy Home

Applicant's Own Ref:

Status: Draft

Tracking Number: MI-01062004-CL-000217-2

Client Details Evidence API/Product Details

Applicant

Applicant Name: Valued Client

Client Id: 9999999

Address: PO Box 1234

Suburb: Melbourne State: VIC

Postcode: 3000 Country: Australia

Phone: Fax:

Email:

Sponsor

Application loaded successfully.

Start SIME Notes Home ... Clearance Appli... Exploring - Images Microsoft Word - S... 030_SIME_MISvie... Local intranet 13:53

Fig. 45. View Draft GMP Clearance Application

Draft Clearance Application

This form is used to open an existing draft clearance application.

Read Only Fields

Status is always “Draft” (Pg 100).

Tracking Number is created by the system once the application has been saved or submitted. It is a unique number which is attached to the application and is used for all future tracking of the application through the system.

Editable fields

The following fields are editable when creating an application or editing an existing draft application. They become non-editable once the application has been submitted.

Applicant's Own Ref is an editable field in which the applicant can place any reference information that may help in identifying the application.

Other

Client Details, Evidence, API/Product Details and *Status* (Pg 100) are as per **New Clearance Application**.

To Submit A GMP Clearance Application

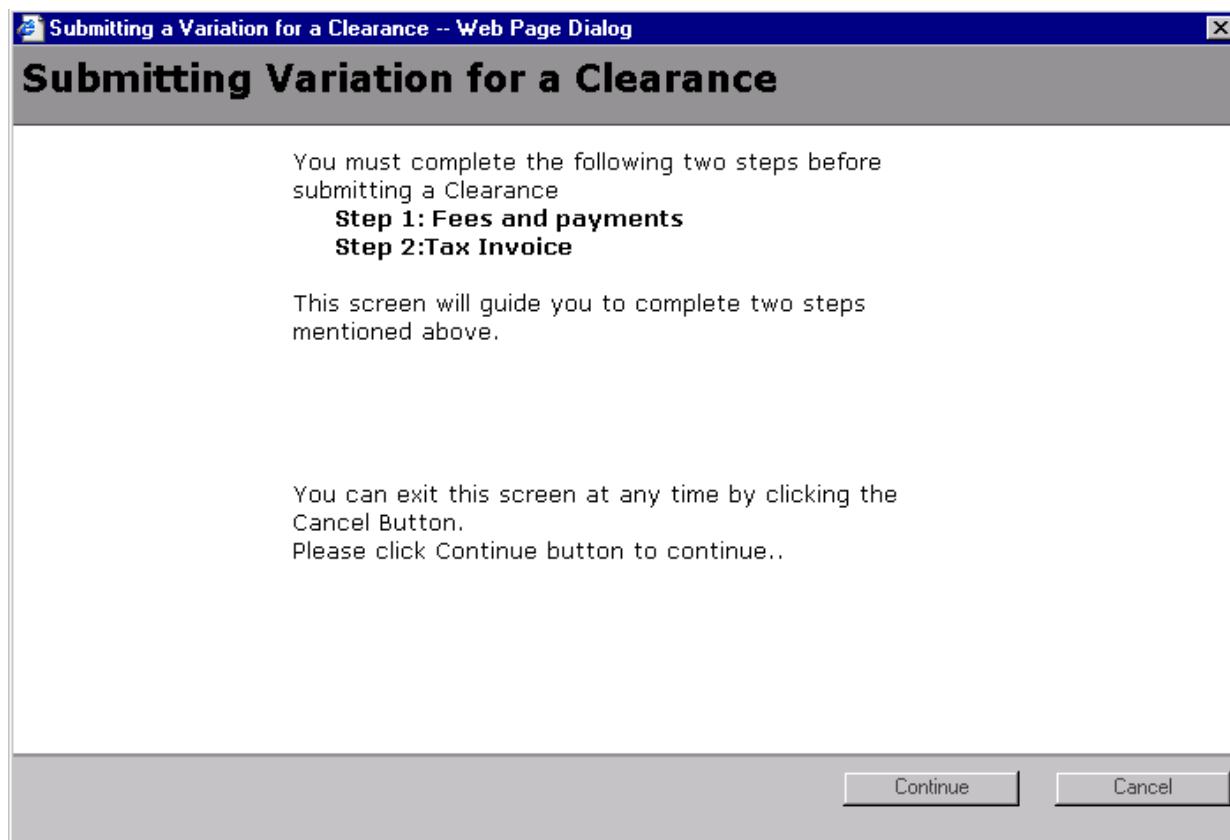


Fig. 46. Submitted Clearance

Submitted Clearance Steps

When submitting an application, a popup box appears requesting a further two steps be actioned as follows:

Step 1 - Fees and Payments

Step 2 - Tax Invoice

Submitting Variation for a Clearance Fees and Payment

Fees: AUD \$1000.00

★ Payment Type: ☒ Cheque ☐ Visa ☐ Bank Card ☐ Mastercard

★ Cheque No:

★ Bank:

Payable to: Testingg fgfgfngdf f

Mail to: Testingg fgfgfngdf f
dsf
sdfd
sf
dsfsd

<< Previous Next >> Cancel

Fig. 47. Fees and Payments

Fees and Payments

All Clearance applications are subject to a fee. This screen allows the user to nominate how payment will be made.

NOTE: If *Visa*, *Bank Card* or *Mastercard* is selected, the payment details must be entered on the *Tax Invoice* (see below). Card details are NOT kept on the system.

Read Only Fields

Fees contains the fee applicable for the type of application.
Payable/Mail To are the details of who the cheque must be made payable to and where to send it.

Editable Fields

Payment Type indicates the payment type. Values are Cheque, Visa, Bank Card & Mastercard.
Cheque No: (Only displayed if Payment Type is CHEQUE) Number of the cheque beeing sent as payment.
Bank: (Only displayed if Payment Type is CHEQUE) Editable field. Name of the bank the cheque has been drawn on.

Submitting a Variation for a Clearance -- Web Page Dialog

Submitting Variation for a Clearance Tax Invoice

Tax Invoice

**This document will be a tax invoice for GST when you make payment.
Please read the information below regarding your payment and ensure it is true and correct.**

Application Details

Tracking Number: MI-03062004-CL-000223-2

Application For:

Applicant's Own Reference:

Applicant's Details

Manufacturer Name:

Manufacturer ID:

Contact Details:

Contact Name: **Client Contact**

Contact Email: wdwqdq

Phone:

Fax:

<< Previous Next >> Cancel

Fig. 48. Tax Invoice

Tax Invoice This form is used to create a tax invoice for a clearance application. The form must, after completion, be printed and one copy sent to TGA.

Read Only Fields *All Fields Except Card Details:* Populated from the contents of the application. This form is the *Tax Invoice for GST* once payment has been made. The details must be read to ensure it is correct. If not, the submission can be cancelled and the application changed to reflect the correct information. Submission can then be done again.

Card Details: (Only displayed if VISA, BANK CARD or MASTERCARD is selected as the Payment Type) Card information written on the printed version of the Tax Invoice will ONLY be used to make payment and is NOT retained in the system.

Card Holders Signature: After clicking *Next* on the *Tax Invoice* page, a "printer friendly" version is displayed which must be printed. The printed page must be faxed to TGA.

View Submitted GMP Clearance Applications

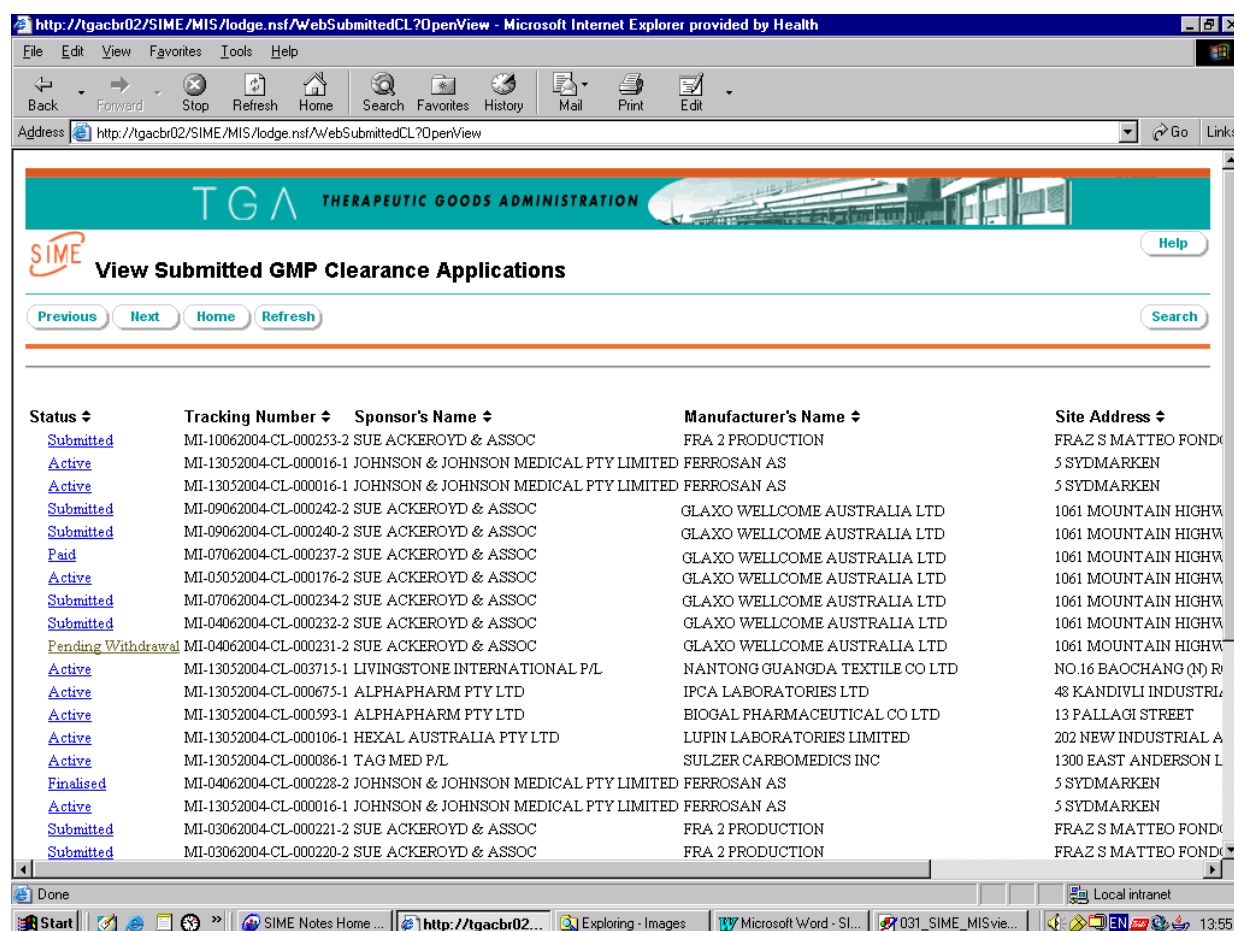


Fig. 49. View Submitted GMP Clearances List

Submitted Clearance List

This screen lists all the clearance applications submitted by the user currently logged in. Clicking on the status will open that application.

Read Only Fields

Status (Pg 100) shows the current status of the application.

Tracking Number is created by the system once the application has been saved or submitted. It is a unique number which is attached to the application and is used for all future tracking of the application through the system.

Sponsor's Name is the name of the sponsor associated with the application.

Manufacturer's Name is the name of the manufacturer associated with the application.

Primary Street Address is the first line of the primary site's address.

Received is the date the application was received.

Fig. 50. View Submitted GMP Clearance Application

Submitted Clearance Application

This form is used to view an application that has been submitted. No changes can be made to the application. If changes are required, the application must be withdrawn and a new draft copy created.

Read Only Fields

Applicant's Own Ref is the applicant's own reference information that may help in identifying the application.

Status (Pg 100) is the current status of the submission within the system.

Tracking Number is created by the system once the application has been saved or submitted. It is a unique number which is attached to the application and is used for all future tracking of the application through the system.

The following field is only displayed when viewing a **variation**.

Original Tracking Number is the tracking number of the original application.

Other

Client Details, Evidence and API/Product Details are as per **New Clearance Application** but cannot be edited.

Fees and Payments is covered in the next section.

Clearance Application - Microsoft Internet Explorer provided by Health

File Edit View Favorites Tools Help

Back Forward Stop Refresh Home Search Favorites History Mail Print Edit

Address <http://tgacbr05/SIME/MIS/lodge.nsf/463b338b6200c3d6ca256e3f007b27e9/5e2f386ceb6c487fca256eb7001e889b?OpenDocument> Go Links

TGA THERAPEUTIC GOODS ADMINISTRATION

SIME Clearance Application Help

Close View Entire App Withdraw New Draft Copy Home

Applicant's Own Ref. For the new production line.
 Status: Submitted
 Tracking Number: MI-18062004-CL-000517-5

Client Details Evidence API/Product Details Fees and Payments

Fees and Payment

Fee:	\$100.11
Payment Type:	Cheque

Application loaded successfully. Local intranet

Start Welcome - Lotus Notes Exploring - Images Microsoft Word - SIME MI... Clearance Applicatio... 16:34

Fig. 51. Submitted Application – Fees & Payments

Fees & Payments

This form displays the fees and payments information relating to the application. It is only displayed while the application is in submit status.

Read Only Fields

Fee is the amount due or paid for the application.

Payment Type is the method of payment.

View Approved GMP Clearances

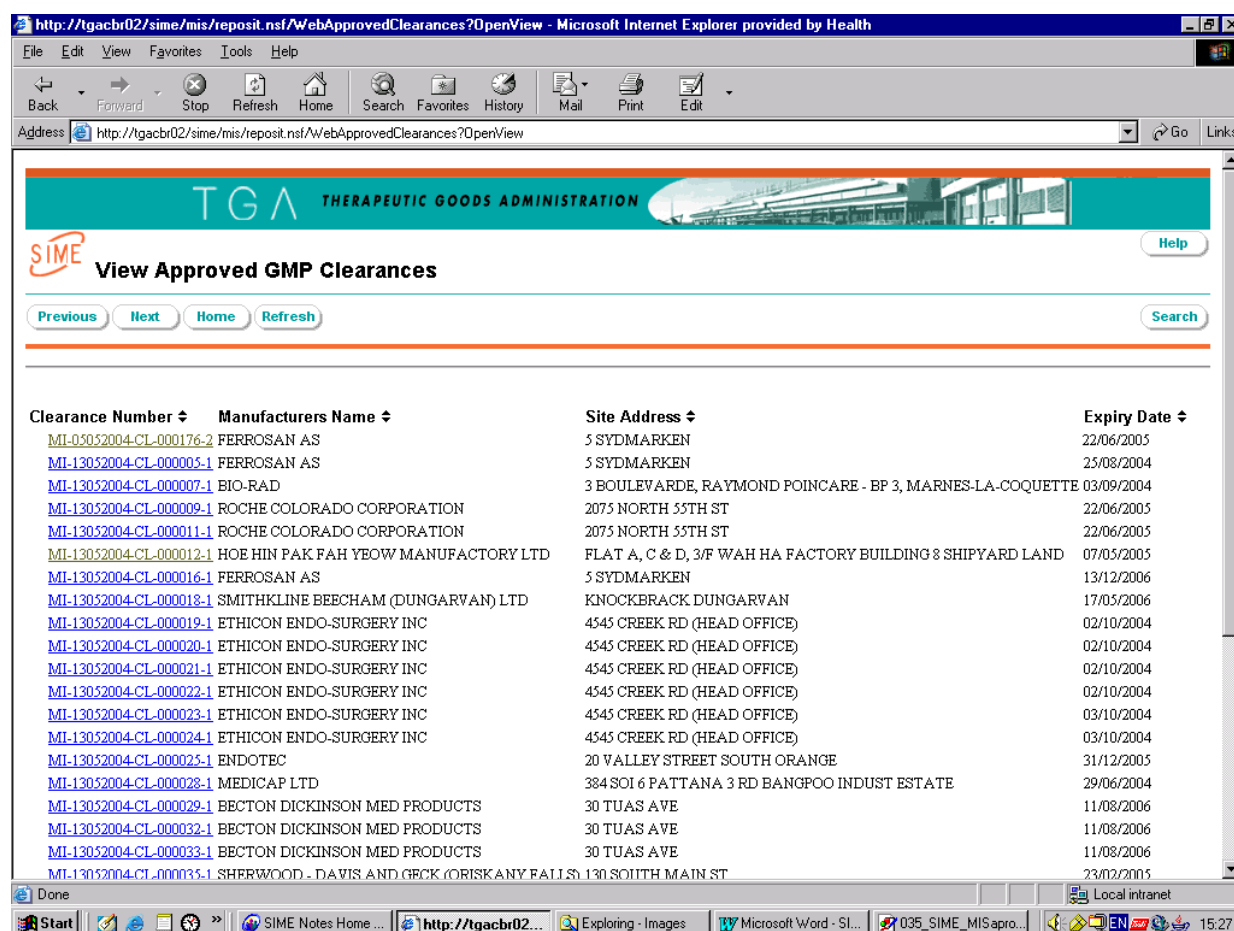


Fig. 52. Approved GMP Clearances List

Approved Clearances List

This screen lists all the approved clearance applications owned by the user currently logged in. Clicking on a clearance number will open that clearance for viewing.

Read Only Fields

Clearance Number is the tracking number that was allocated by the system when the application was created. It is a unique number which is attached to the application and is used for all future tracking of the application through the system.

Manufacturer's Name is the name of the manufacturer associated with the application.

Site Address is the first line of the primary site's address.

Expiry Date is the date the clearance will expire.

Fig. 53. Approved GMP Clearance

Approved Clearance

This form is used to view an approved clearance. No changes can be made but, if changes are required, a variation application to the clearance can be created.

Read Only Fields

Applicant's Own Ref is the applicant's own reference information that may help in identifying the application.

Status (Pg 100) shows the current status of the application.

Tracking Number is created by the system once the application has been saved or submitted. It is a unique number which is attached to the application and is used for all future tracking of the application through the system. Once an application is approved, it becomes the clearance number.

The following field is only displayed when viewing a **variation**.

Original Tracking Number is the tracking number of the original application.

Other

Client Details, Evidence and *API/Product Details* are as per **New Clearance Application** but cannot be edited.

View TGA Data

View All TGA Data

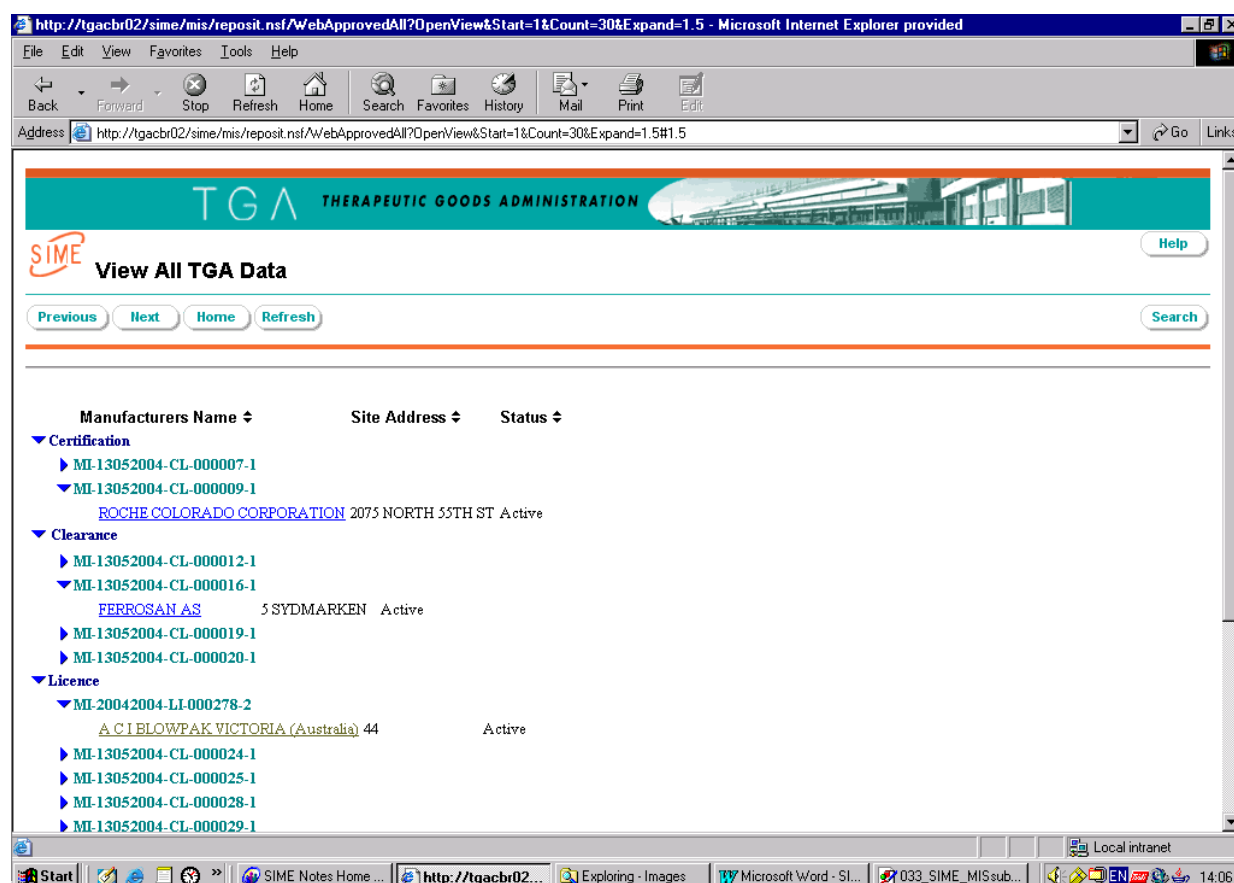


Fig. 54. View All TGA Data List

View all TGA data

This screen lists of all information recorded on TGA's GMP Register that is owned by the user currently logged in. The items are grouped by tracking number within GMP Register type. Clicking on a manufacturer's name will open that application for viewing.

Read Only Fields

Tracking Number is created by the system once the application has been saved or submitted. It is a unique number which is attached to the application and is used for all future tracking of the application through the system.

Manufacturer's Name is the name of the manufacturer associated with the application.

Site Address is the first line of the primary site's address.

Status (Pg 100) shows the current status of the application.

Troubleshooting

I am unable to access my work area homepage	If you are unable to access your work area's homepage, please contact your system administrator. Adjustments may need to be made to your access privileges for your account, or there may be a system wide fault.
I am unable to attach a file	Ask your system administrator to check your account permissions.

APPENDIX A – Manufacturing Items

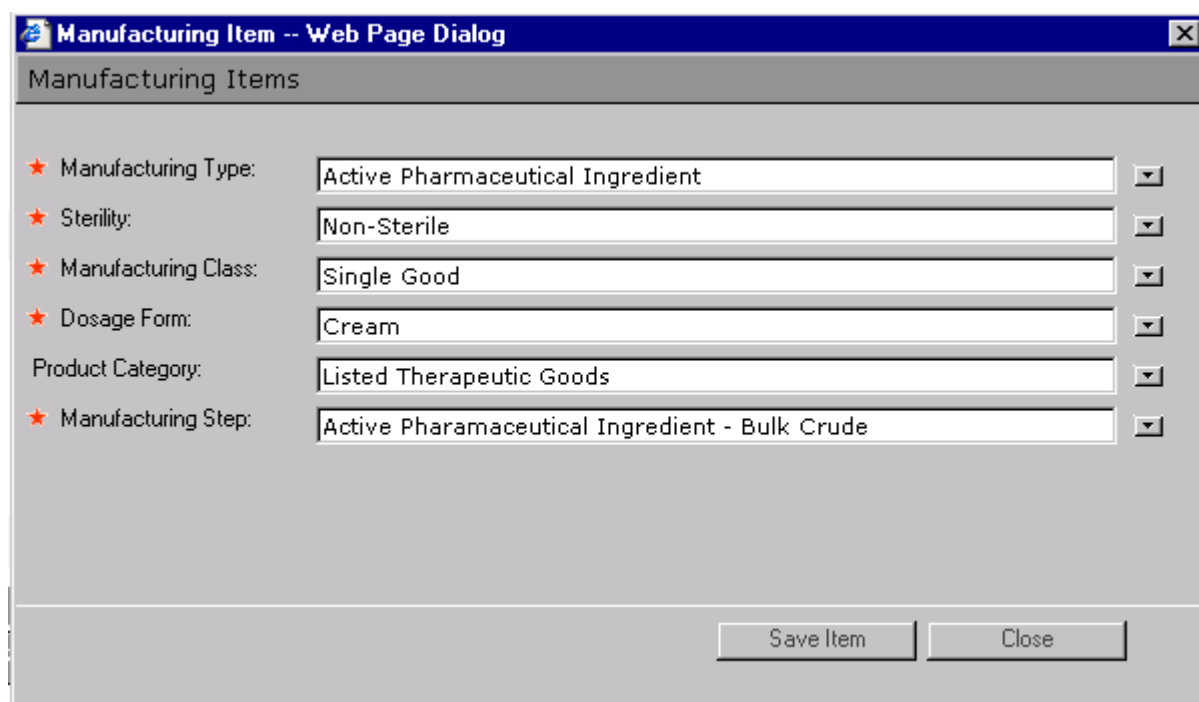


Fig. 55. Manufacturing Items

Manufacturing Items Dialog Wherever Manufacturing Items are required to be input, clicking on the *Add* button brings up a dialog box to enter the item details.

Editable Fields *Manufacturer Type:* The type of product being manufactured.

Sterility: Indicate whether the manufacturing type is sterile or non-sterile.

Manufacturing Class: The class of the manufacturing item.

Dosage Form: The dosage form applicable to the manufacturing item.

Product Category: The product category of the manufacturing item.

Manufacturing Step: The manufacturing step of the manufacturing item.

NOTE: All items can be selected from a drop down list or typed in if not in the list.

APPENDIX B – Status Codes

Draft Applications

Draft: Draft application has been saved by the applicant and is still being worked on. No TGA involvement.

Submitted Applications

Submitted: Application has been submitted by the applicant as is awaiting confirmation of payment of the application fee.

Paid: Application has been submitted and the application fee confirmed as paid. Awaiting commencement of review processing by TGA.

Under Review: Application is being reviewed by TGA.

With Manufacturer: Application is with the applicant/ manufacturer awaiting further information to be provided.

Pending Withdrawal: Application has been withdrawn by the applicant. Awaiting processing by TGA.

Withdrawn: Application has been withdrawn.

Finalised: Application has been finalised and a decision recorded (accepted or rejected). Awaiting expiry of appeal period or process completion by TGA.

Complete: Application has been completed.

Approved Applications

Active: Application has been approved and is active.

Inactive: Application has been approved but is inactive.

Suspended: Licence/Certification has been suspended for a period of time.

Cancelled: Licence/Certification/Clearance has been cancelled.
